COMMENTS OF PHILIP MORRIS USA INC. ("PM USA")

ON THE

PROPOSED NEW YORK FIRE SAFETY STANDARDS FOR CIGARETTES

(TO ADD NEW PART 429 TO TITLE 19 N.Y. COMP. CODES R. & REGS.)

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EXECUTIVE SUMMARY

Philip Morris USA Inc. ("PM USA") supports reasonable regulation requiring cigarettes with reduced ignition propensity ("IP").[1] Because cigarettes are manufactured and distributed nationally, PM USA supports and is working toward the enactment of federal legislation that is consistent with these comments. In the absence of federal legislation, PM USA is making every effort to ensure that it can comply with the New York Fire Safety Law.

PM USA has made significant progress in developing a banded paper technology that allows the production of cigarettes that have reduced IP while remaining reasonably acceptable to adult consumers. Since July 2000, PM USA has incorporated this technology into its Merit cigarette brand styles produced for sale in the United States. PM USA has publicly stated its willingness to license its patents and trade secrets concerning its banded paper technology to other cigarette manufacturers.

The Department of State's Office of Fire Prevention and Control ("OFPC") sought to base the performance standard on existing data developed with respect to the actual performance of commercially viable banded paper cigarettes. Notwithstanding this goal, the proposed test method and performance standard fail to reflect demonstrated commercial technology.

These comments, which are based in part on PM USA's substantial experience in conducting IP testing, seek to continue a constructive dialogue toward reasonable and effective regulation of cigarette IP.

1. The Proposed Test Method Suffers from Certain Critical but Curable Defects.

- **OFPC should adopt the National Institute of Standards and Technology ("NIST") Test.** There is a very substantial difference in how banded and perhaps other cigarettes perform on the American Society of Testing and Materials ("ASTM") Test and how they perform on the NIST Test. Because OFPC relied on NIST Test data in setting the numerical performance standard, compliance with that standard should be measured using the NIST Test.

[1] Throughout these comments, PM USA uses the term "reduced IP" to refer to a lower percentage of full-length burns on a cigarette extinction test, as described in the Proposed Regulation and these comments. PM USA believes that the relationship between reduced IP cigarettes and actual reductions in the number of cigarette-related fires is necessarily unclear at this time. First, reduced IP cigarettes are not "fire safe" -- any product that burns can cause a fire if it is handled carelessly. Second, the real test of whether reduced IP cigarettes reduce fires will be whether there is a significant change in the number of cigarette-related fires experienced after an IP performance standard has gone into effect, something that cannot be known for some time.

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- **OFPC should require all testing laboratories to demonstrate their precision and accuracy by testing control cigarettes prescribed by OFPC.** The repeatability standard in the Proposed Regulation should be modified, because it fails to reflect the substantial testing variability of commercial cigarettes. The Proposed Regulation also does not provide adequate controls to ensure the precision and accuracy of test results, including between different testing laboratories. To address these issues, OFPC should require each laboratory to demonstrate its precision and calibrate its accuracy on highly standardized control cigarettes that meet the performance standard.

2. PM USA Supports a Reasonable and Effective Performance Standard that Requires a Long-Term Production Average of No More than 25 Percent Full-Length Burns ("PFLB") on the NIST Test (10 Layers of Filter Paper).

- **OFPC should require each manufacturer to maintain a three-year cumulative test mean of no more than 25 PFLB on the NIST Test.** With respect to each brand style[2] of cigarette (or IP group, if permitted by OFPC), each manufacturer should be required to:

  - Produce a cumulative mean test result over the first year of production within or below a specified range of 25 PFLB ± 8 PFLB;

  - Produce a cumulative mean test result over the first two years of production within or below a specified (but narrower) range of 25 PFLB ± 3 PFLB;

  - Produce a cumulative mean test result over the first three years of production of no more than 25 PFLB; and

  - Produce, with respect to each subsequent year, a cumulative mean test result over the most recent three years of production of no more than 25 PFLB.

- **PM USA is willing to undertake the substantial effort that would be needed to comply with this standard.** PM USA would have to substantially reduce the IP of nearly all of its existing brands in order to comply with this standard.

- **OFPC can independently verify compliance with this performance standard.** OFPC should require each manufacturer to submit a testing plan to OFPC for its approval and provide OFPC with a replicate sample of all of the cigarettes tested in accordance with this plan so that OFPC can perform its own independent testing.

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[2] Throughout these comments, PM USA uses the term "brand style" to mean a "variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging," which is the definition of "brand style" provided in the Federal Cigarette Labeling and Advertising Act, § 2(8), 15 U.S.C. § 1332(8).

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- **A cumulative test mean appropriately accounts for the substantial amount of manufacturing and testing variability.** Because the performance standard necessarily will be enforced based on highly variable test results, the standard must provide manufacturers with adequate time to perform a sufficient number of test trials (over different production lots or runs, if possible) to verify compliance.

- **Regulatory authorities routinely use mean performance, taking into account statistical variability, to measure the performance of cigarettes and other products.** PM USA's proposal to use cumulative mean test results to measure compliance is consistent with the approach taken in numerous existing regulatory regimes.[3]

3. PM USA Believes that OFPC's Proposed Performance Standard Would Not Advance the Purpose of the Legislation and Would Lead to Serious Unintended Consequences.

- **The Proposed Regulation effectively would impose a performance standard that requires mean test results substantially less than 25 PFLB.** To meet this standard, manufacturers most likely would have to design cigarettes to achieve cumulative mean test results of about 5 PFLB on the NIST Test and perhaps even less on the ASTM Test.

- **The OFPC-proposed performance standard would create substantial uncertainty and could cause long delays related to assessing the toxicity of compliant cigarettes.** All potential cigarette or paper design modifications intended to meet the OFPC-proposed standard would have to be evaluated and deemed acceptable from a toxicological perspective -- a process that could take more than a year depending upon the magnitude of the change.

  - PM USA has already performed several years of toxicological evaluations of cigarettes made with the current banded paper technology. This technology could be applied with minor changes to meet the performance standard proposed by PM USA (a three-year production average of 25 PFLB on the NIST Test). It therefore would not be necessary for PM USA to perform substantial further toxicological evaluations in order for this banded paper technology to be applied to all of PM USA's brand styles.

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[3] For example: (1) the European Union has adopted legislation that uses a mean-based methodology to determine compliance with cigarette smoke yield limits for "tar", nicotine and carbon monoxide; (2) the U.S. Consumer Product Safety Commission frequently uses mean performance to measure compliance with various safety standards; (3) certain environmental regulations adopted by the U.S. Environmental Protection Agency base compliance on mean performance; and (4) New York has adopted mean-based performance standards in at least two other areas involving consumer protection.

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- In contrast, any significant modification of the current technology or any new technology -- as likely would be necessary to comply with the OFPC-proposed standard -- would require a full battery of toxicological tests (approximately 16 months).

- Further, if any modification or new technology resulted in the need for constant or intermittent re-lighting of the cigarettes, it would be very difficult if not impossible to machine smoke these cigarettes using government-accepted standard smoking conditions. Without the ability to perform this critical part of the standard testing battery, it would be difficult and perhaps take substantially more time to evaluate these cigarettes from a toxicological perspective.

- **A performance standard requiring a mean PFLB substantially less than 25, such as OFPC's proposed standard, may trigger substantial purchases of non-IP-compliant cigarettes, thus undermining the purpose of the statute.**

  - PM USA expects that cigarettes complying with OFPC's proposed performance standard would go out more frequently while being smoked and be rejected by a significant number of adult smokers. This could result in substantial consumer purchases of non-IP-compliant cigarettes intended for distribution outside of New York, some of which will be illegal purchases.

  - Such a standard therefore could have the perverse effect of achieving no improvement in the IP of the cigarettes that are actually smoked by New Yorkers. In that event, the proposed performance standard would not achieve the objective of the Fire Safety Law.

  - In contrast, the standard supported by PM USA would both result in a substantial lowering of the IP of nearly every brand in the marketplace and be less likely to cause as many adult smokers to increase their purchases of non-IP-compliant cigarettes. If so, PM USA's proposed standard would do more than the standard proposed by OFPC to lower the IP of cigarettes actually consumed in New York.

- **NYS and NYC tax revenues would be severely reduced by substantial further growth in the purchase of out-of-state cigarettes.** Tax-motivated purchases of cigarettes intended for distribution outside New York already are a serious problem in New York State (including New York City). PM USA believes that the performance standard put forward in the Proposed Regulation would seriously compound New York's cigarette bootlegging[4] problem.

  - If only 10% of consumers who currently purchase cigarettes with a New York tax stamp were to turn to non-IP-compliant cigarettes, the State would lose

[4] In these comments, the terms "bootleg" and "contraband" are used interchangeably to refer to all illegal sales of cigarettes whether of genuine or counterfeit product.

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approximately **$100 million in annual revenue**. The lost tax revenue would be substantially higher if 20%, 30% or some higher percentage of these consumers switched to non-New York State sources. These are realistic possibilities in terms of likely switches to cross-border or bootlegged cigarettes if the standard in the Proposed Regulation were adopted.

- The State would also lose sales tax revenues on these sales. In addition, local governments within New York State would lose sales tax revenue, and New York City would lose substantial tobacco tax revenue.

- **The sale of non-IP-compliant cigarettes in NYS and NYC may also put at risk the livelihoods of thousands of tax-paying, tax-collecting businesses.** The state of New York currently licenses tens of thousands of tobacco dealers. Non-IP-compliant cigarette sales by non-licensed and/or out-of-state vendors will compete with and likely reduce the tobacco sales of many of these lawful dealers, a substantial number of which rely on the sale of cigarettes for one-third or more of their business volume.

- **The standard supported by PM USA could present the same types of risk that are described above but to a much lesser extent.** PM USA believes that cigarette in compliance with its proposed standard would be rejected by fewer adult smokers than would cigarettes under the standard proposed by OFPC. For this reason, PM USA's proposed standard would be less likely to contribute to the consumer demand for non-IP-compliant out-of-state cigarettes. Thus, the adoption of PM USA's proposed standard would more effectively advance the purpose of the legislation without further increasing the risk of substantial losses in tax revenues.

4. OFPC Should Prescribe Certain Requirements Related to the Implementation of the Standard.

- **OFPC should permit manufacturers to test cigarettes in OFPC-approved IP groups that have common performance parameters relevant to IP.** This approach would prevent the unnecessary testing of large numbers cigarettes that are no different for IP performance purposes.

- **OFPC should require each manufacturer to conduct a minimum number of test trials per IP group per year pursuant to an OFPC-approved testing plan.** OFPC should require each manufacturer to submit, for OFPC's review and approval, a proposed test sampling protocol together with the manufacturer's proposed IP group plan, if any. OFPC should require a minimum of 24 trials per year per IP group to provide greater confidence in the statistical significance of the manufacturer's cumulative test results.

- **OFPC should require that each manufacturer annually certify its test data and ongoing compliance with the performance standard.** OFPC should require each manufacturer to file separate certifications with the State for each of its cigarette brand styles or IP groups. However, OFPC should require each manufacturer to file

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only one combined certification -- listing each of the manufacturer's brand styles that are covered by a certification that has been filed with the State -- with each New York licensed agent and wholesale dealer to which the manufacturer sells cigarettes.

- **PM USA urges OFPC to announce a policy of non-enforcement at the wholesale level for a period of 30 days and at the retail level for a period of 120 days following the effective date of the Regulation.** This exercise of enforcement discretion would permit wholesalers and retailers to sell to adult smokers most or all of their normal inventory of non-IP-compliant cigarettes and would prevent a large volume of unsaleable product or product returns that otherwise could trigger substantial costs for the regulated community, as well as the State.

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COMMENTS OF PHILIP MORRIS USA INC. ("PM USA") ON THE PROPOSED NEW YORK FIRE SAFETY STANDARDS FOR CIGARETTES

I. INTRODUCTION

Philip Morris USA Inc. ("PM USA") supports reasonable regulation requiring cigarettes with reduced ignition propensity ("IP"). PM USA has made significant progress in developing a banded paper technology that allows the production of cigarettes that have reduced IP while remaining reasonably acceptable to adult consumers. Since July 2000, PM USA has incorporated this technology into its Merit cigarette brand styles produced for sale in the United States. The Department of State's Office of Fire Prevention and Control ("OFPC") sought to base its proposed performance standard on existing data developed with respect to the actual performance of commercially viable banded paper cigarettes. Notwithstanding this goal, the proposed test method and performance standard fail to reflect demonstrated commercial technology. These comments, which are based in part on PM USA's substantial experience in conducting IP testing, seek to continue a constructive dialogue toward reasonable and effective regulation of cigarette IP.

A. PM USA Supports the Development of Reduced Ignition Propensity Cigarettes and Corresponding Regulatory Requirements.

PM USA is the largest U.S. manufacturer of cigarettes. Its major domestic cigarette brands include Basic, Marlboro, Merit, Parliament and Virginia Slims. PM USA sales currently account for approximately 43.5% of cigarette sales in New York.[5] PM USA has developed, commercialized and marketed materially reduced IP cigarettes in the absence of federal and state regulations mandating such designs.

PM USA supports reasonable regulation requiring cigarettes with reduced IP, which assures effective but reasonable compliance standards and an equitable enforcement scheme under which all market participants are required to comply with those standards. Because cigarettes are manufactured and distributed nationally, PM USA believes that federal legislation should be enacted to address the issue of reduced-IP cigarettes in a uniform way. PM USA supports and will continue to work towards the enactment of federal legislation that is consistent with these comments. PM USA will continue working with regulators, legislators and fire-safety organizations who have a mutual interest in creating a standard that is both technically effective and does not so adversely change the nature of the product as to create a substantial risk that adult smokers will purchase non-IP-compliant cigarettes that are produced for sale in other jurisdictions.

In the absence of federal legislation, PM USA is making every effort to ensure that it can comply with the New York Fire Safety Law, which would establish a

[5] PM USA's STARS database, 52-week period ending March 15, 2003.

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performance standard that uses a "cigarette extinction" testing methodology to measure the relative IP of cigarettes. To that end, PM USA submits these comments on the proposed New York Fire Safety Standards for Cigarettes (the "Proposed Regulation"), prepared by the Department of State's Office of Fire Prevention and Control ("OFPC") and published on Dec. 31, 2002. This regulation would implement Executive Law § 156-c(2)(a)(1) ("Fire Safety Law") and is intended to "set fire safety standards for cigarettes which insure that such cigarettes meet performance standards which limit the risk that such cigarettes will ignite upholstered furniture, mattresses, or other household furnishings."[6]

B. Banded Paper Technology Developed by PM USA Has Been Shown To Reduce IP and Is Commercially Available to Other Manufacturers.

PM USA has been conducting research and development on reduced IP cigarettes for more than 10 years on the development of the fabric and filter paper test methods and the science that underlies those methods and on the development of banded paper technology to reduce the IP of cigarettes. PM USA has shared its data with both NIST and OFPC and published[7] and presented[8] its research in scientific forums.

PM USA has made significant progress in developing a banded paper technology that allows the production of cigarettes that have reduced IP and remain reasonably

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[6] Notice of Proposed Rulemaking, Cover Form at 1 (signed Dec. 19, 2002).

[7] P. Chen et al., *Model of Fabric Smoldering Ignition by Cartridge Heaters*, 16 J. FIRE SCI. 75 (1998); R.W. Dwyer et al., *The Effects of Upholstery Fabric Properties on Fabric Ingitabilities by Smoldering Cigarettes*, 12 J. FIRE SCI. 269 (1994); D.S. Kellogg et al., *The Initiation of Smoldering Combustion in Cellulosic Fabrics*, 16 J. FIRE SCI. 90 (1998); D.S. Kellogg et al., *Smolder Rates of Thin Cellulosic Materials*, 15 J. FIRE SCI. 391 (1997); D. McRae, *Modification of the NIST Test for Measuring the Ignition Propensity of Cigarettes*, 18 J. FIRE SCI. 215 (2000).

[8] R. Garg et al., *The Development of Banded Cigarette Paper to Reduce Fabric Ignition Propensity*, CORESTA CONGRESS, Lisbon, Port. (2000); D.S. Kellogg et al., *Fabric Smolder Mechanism Studies*, 50TH TOBACCO CHEMISTS RESEARCH CONFERENCE, Richmond, Va. (1996); M.L. Watkins et al., *The Thermal Performance of Banded Paper Cigarettes*, CORESTA CONGRESS, Xian, China (2001); M.L. Watkins et al., *Dynamic Characterization of Banded Paper Cigarettes Using Fourier Transform Infrared (FTIR) Spectroscopy and Nuclear Magnetic Resonance (NMR) Imaging Techniques*, CORESTA CONGRESS, Xian, China (2001).

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acceptable to adult smokers.[9] PM USA has U.S. patents[10] related to this technology and has publicly stated its willingness to license its patents and trade secrets, including the results of its extensive toxicological testing concerning banded paper technology, to other cigarette manufacturers.

In January 2000, PM USA announced its intention to conduct consumer research and retail test marketing of cigarettes manufactured with banded cigarette paper. Following that announcement, the U.S. Federal Trade Commission requested the National Institute of Standards and Technology of the United States Department of Commerce ("NIST") to "conduct tests to determine whether and to what extent this [banded] cigarette does reduce the risk of ignition."[11] NIST subsequently concluded that cigarettes manufactured with PM USA's banded cigarette paper have a lower relative IP than the same cigarettes manufactured with conventional cigarette paper. NIST's findings were published in NIST Technical Note 1436, *Relative Ignition Propensity of Test Market Cigarettes*, which is included as Attachment 1 to these comments. This technical note includes different methodologies for measuring the IP of cigarettes, including the "Cigarette Extinction Method" which is described in Appendix D to the NIST Technical Note (the "NIST Test").

Beginning in July 2000, PM USA began shipping nationally all of its Merit brand styles of PaperSelect cigarettes with banded paper, and all Merit brand packs and cartons now bear the PaperSelect™ logo. To date, and to the best of PM USA's knowledge, the Merit family brand styles are the only nationally available commercial cigarettes that use a specific technology designed for lowering IP.

PM USA's banded paper technology involves the application of bands of ultra-thin paper (in the case of Merit cigarettes, approximately 6.5 mm wide and spaced 20.5 mm apart) on conventional cigarette paper during the papermaking process. These bands become an integral part of the cigarette paper. The function of the bands is to limit diffusion of oxygen to the coal of the cigarette. Thus, they essentially act as "speed

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[9] PM USA has found that cigarettes with banded paper have reduced IP compared to conventional cigarettes on both fabric, including so-called "reversal" fabrics, and filter paper (cigarette extinction) tests. PM USA continues to conduct research and development today on improved IP tests, including full-scale fire testing, and the improvement of banded paper technology.

[10] U.S. Patent No. 5,263,999 "Smoking Article Wrapper for Controlling Burn Rate and Method for Making Same" (issued Nov. 23, 1993); U.S. Patent No. 5,417,228 "Smoking Article Wrapper for Controlling Burn Rate and Method for Making Same" (issued May 23, 1995); U.S. Patent No. 5,474,095 "Paper Having Crossdirectional Regions of Variable Basis Weight" (issued Dec. 12, 1995); U.S. Patent No. 5,534,114 "Method and Apparatus for Applying a Material to a Web" (issued July 9, 1996); U.S. Patent No. 5,966,218 "Bobbin Optical Inspection System" (issued Oct. 12, 1999); U.S. Patent No. 5,997,691 "Method and Apparatus for Applying a Material to a Web" (issued Dec. 7, 1999); U.S. Patent No. 6,020,969 "Cigarette Making Machine Including Band Inspection" (issued Feb. 1, 2000); U.S. Patent No. 6,198,537 "Optical Inspection System for the Manufacture of Banded Cigarette Paper" (issued Mar. 6, 2001).

[11] May 15, 2000 letter from Joan Z. Bernstein of the Federal Trade Commission to Jack E. Snell of NIST.

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bumps" to slow down the rate at which the cigarette burns as the lit end crosses over them. The lower burning rate results from less air reaching the lit tobacco, due to the lower air permeability of the paper in the bands as compared to the higher permeability of the paper between the bands. The change in burn rate increases the probability that the cigarette will extinguish when placed on many fabric types and therefore decreases the probability that the cigarette will ignite those fabrics. Studies conducted by PM USA over more than 10 years support the effectiveness of banded paper technology for reducing the likelihood of fabric ignition from smoldering cigarettes.[12]

Even though cigarettes manufactured with banded paper show reduced IP, anything that burns -- including cigarettes -- can cause a fire if handled carelessly. Therefore, cigarettes manufactured with banded cigarette paper are not "fire safe"; they must be handled and disposed of no less carefully than other cigarettes.

C. OFPC Has Considered and Should Continue To Consider the Performance of Banded Paper Cigarettes While Developing an Appropriate Performance Standard.

OFPC's November 15, 2002 study document, *Derivation of a Cigarette Fire Safety Performance Standard* ("Performance Standard Study Document"), summarizes test data developed by OFPC in support of the Proposed Regulation and notes that cigarettes from the New York market using "banded paper" demonstrated lower IP than did unbanded cigarettes. OFPC states that these banded paper cigarettes "were specifically designed to limit [IP] and can be potentially used to guide the design [of] a performance standard." *Id.* at 3. OFPC further states:

> The performance [of] the currently marketed "banded" paper cigarette results will be used to inform [OFPC's] choice of [the regulation's performance] standard. These appear to be the only cigarettes in the marketplace tested so far that are specifically designed to lower [IP]. Referring to this data should not be construed as an endorsement of a particular technology or manufacturer. New technology for lowering [IP] will be assessed as it becomes available.

Id. at 7. Also, OFPC's Regulatory Impact Statement ("RIS") refers to "banded cigarettes" as being "the only technology known to OFPC at this time to feasibly meet the performance standard stated in section 4 of the proposed rule." RIS at 3. As noted, PM USA's cigarettes are the only cigarettes that currently use a banded paper technology, and thus are the only available source for such performance data.

Although OFPC expressed an intent to base the performance standard on existing data developed with respect to the actual performance of PM USA's banded paper, the

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[12] *See supra* at 2.

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standard in the Proposed Regulation is not supported by the existing data. Despite PM USA's substantial efforts to reduce the IP of its Merit cigarettes, based on both PM USA's and OFPC's test results, none of the Merit brand styles appears to meet the performance standard proposed by OFPC, as discussed *infra* at 20-21.

There are two principal reasons for the large gap between the Proposed Standard and the existing commercial technology. First, the test method that is incorporated into the Proposed Regulation is substantially different from the test method that OFPC used to assess the performance of PM USA's banded paper cigarettes. Second, OFPC expressed the proposed performance standard as a "ceiling", as opposed to a mean, which is a key difference given the substantial variability inherent in the test method and in commercial cigarettes.

Because OFPC's Proposed Regulation fails to reflect demonstrated commercial technology, it should be modified in certain key respects. If the Proposed Regulation were modified to reflect PM USA's comments, the performance standard would still significantly reduce IP and would require substantial further efforts by PM USA to achieve compliance with the standard.

II. COMMENTS ON THE TESTING METHOD

Section 3 of the Proposed Regulation, "Test Method", would measure certification and compliance using a cigarette extinction test performed in accordance with the American Society of Testing and Materials ("ASTM") Standard E2187-02b, *Standard Test Method for Measuring the Ignition Strength of Cigarettes* (the "ASTM Test").[13]

In general, PM USA supports OFPC's proposal to use a cigarette extinction test to measure compliance with an IP performance standard.[14] However, PM USA does have serious concerns about the implementation of the test method as proposed by OFPC.

As a threshold matter, neither the NIST Test (discussed *supra* at 3) nor the ASTM Test was devised to measure compliance with any particular performance standard or the relationship between any specific performance on the test and the risk of cigarette-related

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[13] In addition, proposed Section 3 would require that: (1) testing be conducted on 10 layers of filter paper; (2) 40 replicate tests comprise a complete test trial for each cigarette tested; (3) the regulation's performance standard be applied only to a complete test trial; (4) laboratories conducting testing implement a quality control and quality assurance program that includes a procedure to determine the long-term repeatability of the testing results; and (5) the repeatability value be no greater than 19% pursuant to the regulation's performance standard (with "repeatability" to be defined in Section 2(d) as "the range of values within which differences among repeat cigarette test trial results will fall 95% of the time in the same laboratory").

[14] The extinction test method has important advantages over other possible test methods (*e.g.*, the Mock-Up Ignition Test), particularly when incorporated into a regulatory framework that is to be implemented in a consistent manner by numerous parties.

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fires. Rather, both tests were designed to determine whether there is a measurable difference between the IP of two different cigarettes. *See, e.g.*, ASTM Test at 5.2 ("This test method enables comparison of the relative [IP] of different cigarette designs."). Because both tests were designed to measure relative IP, each test involves the possibility of testing on three different substrates -- 15, 10 and 3 layers of filter paper.

Further, neither the NIST nor the ASTM Test purports to establish any specific relationship between test performance and the risk of cigarette-related fires. Rather, relying solely upon data developed using the NIST Test, ASTM concludes only that there is some relationship between test performance and expected real-world impact on cigarette-related fires. *See* ASTM Test at 7 (XI. Ignition Susceptibility of Substrate Assemblies) ("It is thus expected that significantly improved performance on this test method will lead to reduced ignitions of soft furnishings."). However, neither the NIST nor the ASTM Test provides any basis for predicting the quantitative extent to which improved performance on the test might translate into an actual reduction in cigarette-related fires. *See supra*, Executive Summary at iv, n.1.

Against this backdrop, it is not surprising that OFPC's proposed use of the ASTM Test to implement a particular numeric performance standard creates issues that necessarily were not addressed by either ASTM or NIST. The following comments and the technical appendices address these issues.

A. Given the Material Differences Between the NIST and ASTM Tests, OFPC Should Adopt the NIST Test.

Although the ASTM and NIST Tests are both cigarette extinction tests, there are critical differences between the two tests, including substantial experience with the NIST Test, which is not transferable to the ASTM Test.

Contrary to certain statements in the ASTM Test, the technical work that underlies the NIST Test cannot simply be applied to the ASTM Test because of the substantial differences between the two tests. Thus, because the NIST Test is much further developed in various technical respects, it would take OFPC less time to

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promulgate a performance standard that relies on the NIST Test than it would to promulgate a standard that relies on the ASTM Test.[15]

Appendix A to these comments provides a detailed comparison between, and discussion of, the ASTM and NIST Tests.[16] Among other things, it includes a detailed explanation (including testing data) showing that the performance of banded (and perhaps other) cigarettes on the ASTM Test will differ substantially from their performance on the NIST Test. The ASTM Test cited by OFPC was approved only on December 10, 2002, just a few weeks before OFPC published the Proposed Regulation.[17] PM USA's current (but necessarily limited) test data indicates that the mean performance of banded cigarettes on the ASTM Test might be approximately 15-25 percentage points higher (in terms of the percent of full length burns) ("PFLB") than the mean performance of identical cigarettes on the NIST Test.[18]

Thus, OFPC should adopt the NIST Test because it has several critical advantages over the ASTM Test: (1) OFPC relied on data from the NIST Test in setting the proposed performance standard, and the limited data available show that the ASTM Test produces substantially different test results, at least with respect to banded cigarettes; (2) the NIST Test has been correlated with ignition tests on fabrics, while the ASTM Test has not; (3) the NIST Test has been evaluated between multiple laboratories, while the

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[15] OFPC apparently has concluded that the ASTM and NIST Tests are the same, at least in all material elements relevant to the development and implementation of the proposed performance standard. For example, OFPC's Performance Standard Study Document states that the State's testing program has used the NIST Test "which is now [the ASTM Test]". Performance Standard Study Document at 1. OFPC cited the Performance Standard Study Document in its Regulatory Impact Statement as one of the three studies that served as a basis for the Proposed Regulation. RIS at 3-4. However, to PM USA's knowledge, all of the cigarette testing performed to date and considered as a basis for OFPC's proposed IP performance standard has employed the NIST Test. PM USA likewise has used the NIST Test in performing a very substantial amount of cigarette IP testing on a wide range of PM USA commercial and prototype cigarettes that incorporate PM USA's IP-reduction technology. As discussed in Appendix A, PM USA has implemented both the NIST and ASTM Tests with minor modifications in order to increase throughput or to comport with PM USA's general cigarette testing practices.

[16] Appendix A also addresses certain technical issues related to the operation of the ASTM Test. In addition to raising these issues in Appendix A, PM USA plans to raise them directly with ASTM.

[17] It has taken some time for PM USA to obtain the equipment necessary and to prepare properly its laboratories to conduct the ASTM Test. Thus, until very recently the ASTM Test was not available for use in generating data.

[18] The magnitude of this tested difference in performance was for a cigarette that is in the range of compliance with PM USA's proposed performance standard, discussed, *infra*, at 15–17. PM USA is in the process of conducting further tests related to the differences between the NIST and ASTM Tests.

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ASTM Test has not; and (4) the NIST Test has been evaluated on a range of cigarettes, while the ASTM Test has not.[19]

B. The Proposed Rule Substantially Underestimates the Testing Variability of Commercial Cigarettes; OFPC Should Require All Testing Laboratories To Demonstrate Their Precision and Accuracy by Testing Control Cigarettes Prescribed by OFPC.

The technical appendices to these comments provide PM USA's detailed comments on the bias (accuracy) and precision of the NIST and ASTM Tests.[20] In sum, PM USA believes that the performance of commercial cigarettes on both the NIST and ASTM Tests will be substantially more variable than has been estimated by either ASTM or OFPC. In addition, it appears that ASTM may have significantly underestimated the variability of test results that could be produced by different laboratories or laboratory operators properly conducting the test.[21] Because ASTM has underestimated the variability in performance of commercial cigarettes on the ASTM Test, OFPC's proposed testing repeatability standard is unworkable. PM USA has had substantial experience conducting the NIST Test. Although PM USA believes that it can meet a scientifically valid repeatability criterion, it does not believe that it can satisfy the repeatability standard in the Proposed Regulation. Further, PM USA urges OFPC to establish more detailed quality control and calibration requirements for testing laboratories.

PM USA believes that the final rule should address three critical aspects of laboratory quality: precision, accuracy and certification. Precision should not be evaluated using commercial cigarettes because the underlying product variation will obscure the results. Instead, precision should be measured by generating test data for highly standardized control cigarettes of known IP that meet the performance standard, with those results used to set the standard for precision. Similarly, OFPC should require any laboratory that wishes to conduct testing for the purpose of compliance with and enforcement of the regulation to meet established requirements of accuracy using such control cigarettes and be certified by some authoritative body.

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[19] If OFPC decides to require use of the ASTM Test notwithstanding the issues raised in these comments, it should adjust the numerical standard to require performance on the ASTM Test equivalent to a 25 PFLB performance on the NIST Test (using 10 layers of filter paper). PM USA's current data suggest that this equivalent standard would be approximately 40 to 50 PFLB on the ASTM Test (using 10 layers of filter paper). However, as discussed in Appendix A to these comments, further testing would be required to confirm the magnitude of the difference in the test results between these two tests.

[20] Appendices B and C present and assess PM USA's Merit test data, including an assessment of the test repeatability and reproducibility associated with these test results. Appendices D and E further address issues related to laboratory repeatability and reproducibility.

[21] PM USA remains willing to discuss with OFPC, ASTM and others PM USA's conclusions regarding the level of testing variability that should be expected for manufactured cigarettes on the NIST Test. Due to limited experience in running the ASTM Test, the variability of the ASTM Test is unknown. However, notwithstanding certain differences between these two tests, PM USA would expect them to produce similar testing variability.

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OFPC should prescribe the design and corresponding target PFLB of the control cigarettes. Because OFPC relied on the performance of banded cigarettes in prescribing the performance standard, PM USA believes that the control cigarettes should include a banded cigarette with an IP performance in the range of 25 PFLB. As discussed in detail in Appendix E to these comments, PM USA stands ready to assist OFPC with respect to the technical issues related to the development, production, testing and/or laboratory-control application of such control cigarettes. PM USA believes that all of the necessary requirements for developing the accuracy, precision and certification of the test method could be achieved within one year.

* * *

In accordance with this and other parts of these comments, PM USA suggests that Section 3 of the Proposed Regulation be amended to read as follows:

> "3. Test Method.
>
> "(a) The test required by section 1 shall be conducted in accordance with "Relative Ignition Propensity of Test Market Cigarettes--National Institute of Standards and Technology--NIST Technical Note 1436, January, 2001--Appendix D: Cigarette Extinction Method". This standard may be obtained from the publisher at NIST Public Inquiries, NIST, 100 Bureau Drive, Stop 3460, Gaithersburg, Md., 20899-3460. This material is available for public inspection and distribution at the Office of Fire Prevention and Control of the Department of State at 41 State Street, Albany, New York 12231.
>
> "(b) Testing shall be conducted on 10 layers of filter paper.
>
> "(c) Forty replicate tests shall comprise a complete test trial for each cigarette tested.
>
> "(d) The performance standard required by section 4 shall be applied to complete test trials conducted under a testing plan approved in accordance with subsection (f) and to any compliance testing conducted in accordance with section 9.
>
> "(e) Laboratories conducting testing in accordance with this section shall implement a quality control and quality assurance program that includes a procedure that will determine the long-term repeatability and accuracy of the testing results. The repeatability value shall be measured by conducting tests using a control cigarette[s] and shall be

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within the range specified by the Office of Fire Prevention and Control.[22]

"(f) Within 45 days after the adoption of the performance standard in section 4, each manufacturer shall submit a proposed testing plan for approval by the Office of Fire Prevention and Control. Once approved, such testing plan shall continue to be used by the manufacturer except to the extent changes in such plan have been approved by the Office of Fire Prevention and Control. Each proposed testing plan shall:

"(1) identify the brand styles proposed to comprise any ignition propensity groups and explain the rationale for such groupings;

"(2) explain the proposed test sampling protocol of the testing plan and demonstrate that such protocol will produce randomized and representative samplings of all brand styles within each proposed ignition propensity group;

"(3) provide for a minimum of 24 complete test trials per year (over different production lots or runs, if possible)[23] for each brand style or ignition propensity group;

"(4) identify, and provide a description of the ignition propensity of, any cigarettes which cannot be tested using the testing methodology referred to in subsection (a) because of unique or nontraditional characteristics and for which approval is being sought pursuant to subsection (g), along with a proposed testing methodology and proposed performance standard for such cigarettes;

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[22] The term "repeatability" should be defined to mean "the range of values specified by the Office of Fire Prevention and Control within which differences among repeat cigarette test trial results for the control cigarette will fall 95% of the time in the same laboratory." The term "control cigarette" should be defined to mean "a reference cigarette of a known range of ignition propensity performance that is produced to specifications provided by the Office of Fire Prevention and Control and used as part of a quality control and quality assurance program to verify the accuracy and testing repeatability of a testing laboratory." The term "testing laboratory" should be defined to mean "a laboratory that meets a quality control and quality assurance program prescribed by the Office of Fire Prevention and that is certified as qualified to conduct testing in accordance with section 3 or section 8 by some authoritative body, as determined by the Office of Fire Prevention and Control."

[23] The term "production lot or run" should be defined to mean "a production batch or, if a manufacturer uses a continuous production process, a specified segment of such production on one machine (such as a segment specified to indicate a change in shifts of production employees)."

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"(5) if the manufacturer is seeking to implement changes to a testing plan approved under this subsection, identify and explain the purposes for any such proposed changes; and

"(6) specify any information which the manufacturer claims as exempt from public disclosure as trade secret or other confidential information pursuant to N.Y. Public Officers Law, § 87(2)(d).

"(g) With respect to any cigarette that cannot be tested using the testing methodology referred to in subsection (a) because of unique or nontraditional characteristics, the Office of Fire Prevention and Control shall accept a testing methodology and performance standard that are proposed by the manufacturer or manufacturers of the cigarette if, after review of the description of the ignition propensity of the cigarette, the proposed testing methodology, and the proposed performance standard, the Office of Fire Prevention and Control determines that the cigarette has an ignition propensity equivalent to or less than cigarettes that meet the performance standard in section 4."

III. COMMENTS ON THE PERFORMANCE STANDARD

A. PM USA Supports a Reasonable and Effective Performance Standard that Requires a Long-Term Production Average of No More Than 25 PFLB on the NIST Test (10 Layers of Filter Paper).

PM USA supports the adoption of a performance standard that requires a long-term production average of no more than 25 PFLB on the NIST Test using a 10-layer filter paper substrate. PM USA proposes that the State enforce this standard in two ways. First, OFPC should impose annual testing obligations and testing performance requirements on cigarette manufacturers. Second, OFPC should require that each manufacturer submit to OFPC replicates of these manufacturer-tested cigarettes, so that OFPC can independently verify compliance.

PM USA would have to reduce substantially the IP of nearly all of its existing brands in order to comply with its proposed standard. Based on PM USA's extensive testing results,[24] its Merit Lights cigarettes have a cumulative test mean through the end of 2002 somewhat above 25 PFLB on the NIST Test (using 10 layers of filter paper). Further, because the tobacco blends for certain other brand styles present greater challenges with respect to IP -- as compared to the tobacco blend used in Merit Lights -- PM USA would have an even more difficult task to reduce the IP of these other brand

[24] PM USA's Merit testing data are provided and discussed in detail in Appendices B and C to these comments.

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styles to the degree necessary to achieve compliance with its proposed performance standard.

Nevertheless, PM USA is willing to commit to the effort required to meet its proposed performance standard, which it believes is stringent but workable.

1. Given the expected variability in performance on the NIST Test, the performance standard should be based on the *cumulative mean test results over a large number of test trials.*

Because of the extent of the expected variability in test results, there is a substantial difference between a standard established with reference to cumulative mean test results and a standard established with reference to test results on any single test trial. For this reason, PM USA supports a standard expressed in terms of mean performance that appropriately takes into account statistical variability.

As discussed in more detail throughout the technical appendices to these comments, ASTM has substantially underestimated the testing variability that should be expected when measuring the IP of commercial cigarette brands over time on a cigarette extinction test. Based on its extensive testing of Merit cigarettes on the NIST Test,[25] PM USA believes that test results will vary substantially for commercial cigarettes on either the ASTM or NIST Tests.

More specifically, PM USA believes that test results for commercial cigarette brands are likely to have a standard deviation from the testing mean substantially larger than the 6.86 PFLB standard deviation provided by ASTM and assumed in the Proposed Regulation. PM USA has conducted a substantial number of NIST Test trials on 7 separate brand styles of its Merit cigarettes. As shown in the table below, the number of test trials performed on each of these brand styles range from 11 to 17, and the standard deviation of the test results from the respective means ranges from 6.3 to 22.88 PFLB.

Brand Style	Number of Test Trials	Standard Deviation (in PFLBs)	Mean Test Result (in PFLBs)
Merit Lights KS Reg.	14	15.40	34.38
Merit Lights 100 Reg.	16	22.88	27.47
Merit UL KS Men.	12	16.66	25.61
Merit UL KS Reg.	17	13.42	14.71
Merit UL 100 Reg.	15	22.03	20.07
Merit ULTM KS Reg.	11	6.30	7.29
Merit ULTM 100 Reg.	14	10.36	7.51

[25] The results of PM USA's IP testing of Merit cigarettes are discussed in more detail in Appendices B and C to these comments.

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Most of these actual standard deviations are more than twice as large as the standard deviation provided by ASTM and reflected by the Proposed Regulation's repeatability standard. As demonstrated below, this difference has direct bearing on the establishment of an appropriate performance standard.

For example, the following statistical conclusions can be made with respect to a hypothetical cigarette brand style (similar to Merit Lights) that has an actual long-term production mean[26] of 25 PFLB on the NIST Test (10 layers of filter paper) and that produces test results with a standard deviation of 15 PFLB from the mean:

- For any one test trial of 40 cigarettes, the test trial result will have a margin of error (at a 99% confidence level)[27] of about ±39 PFLB. That is, 99% of the test results for a cigarette with an actual long-term production mean of 25 PFLB would be expected to fall between 0 and 64 PFLB.

- After conducting 10 test trials (over different production lots or runs), the cumulative mean of the test results will have a margin of error (at a 99% confidence level) of about ±12 PFLB. That is, after 10 test trials (over different production lots or runs), there is a 99% probability that the cumulative mean of the test trial results for a cigarette with an actual long-term production mean of 25 PFLB will be between 13 and 37 PFLB.

- After conducting 50 test trials (over different production lots or runs), the cumulative mean of the test results will have a margin of error (at a 99% confidence level) of about ±5 PFLB. That is, after 50 test trials (over different production lots or runs), there is a 99% probability that the cumulative mean of the test trial results for a cigarette with an actual long-term production mean of 25 PFLB will be between 20 and 30 PFLB.

As demonstrated by this example, a standard that relies on the cumulative mean of multiple test results (over different production lots or runs) will be far more accurate at measuring compliance than will be a standard that is expressed with reference to the results on any particular test trial. Further, as more test results are incorporated into the cumulative test mean, the test results will more precisely pinpoint the actual production mean of the cigarette.

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[26] Actual long-term production mean refers to the average PFLB of all cigarettes of a certain brand style or within an IP group that are produced over an extended time period.

[27] "Confidence interval is a range of values that includes (with a preassigned probability called confidence interval) the true value of a population parameter. Confidence limits are the upper and lower boundaries of the confidence interval. Confidence level is the proportion of times in the long run that an assertion about the value of a population parameter is correct." JOSEPH M. JURAN & A. BLANTON GODFREY, JURAN'S QUALITY HANDBOOK 44.42 (5th ed.). Because PM USA will be conducting thousands of IP test trials to comply with the regulations, even low probability outcomes will occur eventually. Thus, any standard based on a low number of test trials is unworkable unless it incorporates a wide confidence ("plus or minus") limit.

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2. Regulatory authorities routinely use mean performance, taking into account statistical variability, to measure the performance of cigarettes and other products.

PM USA's proposal to use cumulative mean test results to measure compliance is consistent with the approach taken in numerous existing regulatory regimes.

For example, the European Union has adopted a Directive to its Member States that requires use of a mean-based methodology to determine compliance with cigarette smoke yield limits for "tar", nicotine and carbon monoxide. Under this Directive, constituent smoke yields are determined through an averaging testing methodology that allows for a ±20% confidence interval (giving a total confidence band of 40%) for cigarettes tested "at one point in time," and a ±15% confidence interval (confidence band of 30%) for cigarettes tested "over a period of time". INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, STANDARD 8243: CIGARETTES -- SAMPLING § 7.3.[28]

The U.S. Consumer Product Safety Commission ("CPSC") also uses mean performance to measure compliance with various safety standards. For example, CPSC determines compliance with flammability standards adopted pursuant to the Flammable Fabrics Act for clothing textiles, vinyl plastic film, and children's sleepwear by taking the mean performance of multiple specimens subjected to flammability testing. 16 C.F.R. § 1610.4. Thus, the regulations contemplate that the flammability rating determined for a particular garment might be exceeded by the performance of some samples in individual flammability tests.[29] Mean performance is a compliance measure for numerous other articles regulated by CPSC pursuant to the Consumer Product Safety Act and the Hazardous Substances Act.[30]

Certain environmental regulations adopted by the U.S. Environmental Protection Agency ("EPA") also base compliance on mean performance. This is the case, for example, with some regulations adopted pursuant to the Clean Air Act. Factories and power plants, the primary targets of these regulations, emit pollutants in varying levels based upon factors such as demand, available fuel inputs, and even the weather. To account for this variation, clean air regulations typically require compliance with

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[28] ISO Standard 8243 also provides that for cigarettes with less than 7 mg of "tar", the confidence interval cannot be smaller than ± 1 mg for "tar" and ± 0.1 mg for nicotine. *Id.* Thus, the confidence intervals are even wider than 15% and 20% for these lower "tar" cigarettes.

[29] Moreover, the flammability standard for clothing textiles explicitly recommends that compliance testing programs account for the high variability of certain fabrics by "test[ing] a sufficient number of samples to provide adequate assurance that such . . . products comply" with the flammability standard. 16 C.F.R. § 1610.62(b).

[30] These articles include architectural glazing materials (16 C.F.R. § 1201), swimming pool slides (16 C.F.R. § 1207), primary irritant substances (16 C.F.R. § 1500.41), flammable substances (16 C.F.R. § 1500.43), self-pressurized containers (16 C.F.R. § 1500.46), caps for toy guns (16 C.F.R. § 1500.47), and bicycle tire sidewalls and rims (16 C.F.R. § 1512.18).

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emissions regulations based on average emissions over a period of time, generally three months or a year.[31] EPA's regulation of the performance of heavy-duty diesel engines also provides substantial flexibility for compliance with the applicable standard notwithstanding test failures by particular engines.[32]

New York also has adopted mean-based performance standards in at least two areas involving consumer protection. First, New York's regulation for bottled water contamination measures compliance with applicable standards based on an average of the performance of three test samples.[33] Second, New York has adopted uniform regulations developed by NIST that incorporate a mean-based performance measure for consumer package contents.[34] Under these regulations, the content of a consumer package must, on average, equal or exceed the content stated on the package label, allowing for a 97% confidence band.[35]

In addition, averaging is permissible under the standard developed by Underwriters Laboratories to evaluate combustion properties of building materials.[36]

These are but a few examples of the use of mean performance standards in other regulatory regimes. They demonstrate that in many contexts regulators and standard-setting bodies have determined that a mean performance measure, taking into account statistical variability, is a sound way to ensure compliance with regulatory standards and objectives.

3. OFPC should require each manufacturer to maintain a three-year cumulative test mean of no more than 25 PFLB on the NIST Test.

PM USA supports the establishment of an IP performance standard for each brand style of cigarettes (or IP group, if permitted by OFPC, *see infra* pp. 30-32) that requires a three-year running test mean of 25 PFLB. PM USA believes that a cumulative test mean

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[31] For example the National Ambient Air Quality Standards are typically expressed in terms of annual and 24-hour means. *E.g.*, 40 C.F.R. § 50.4 (standards for sulfur dioxide). The 24-hour standards are substantially higher than the annual means to account for daily fluctuations. Also, the regulations allow for the 24-hour standards to be exceeded a limited number of times during the calendar year. *Id.*

[32] In assessing whether an engine design complies with the standard, EPA regulations account for the variability in the performance of such engines by permitting a test failure rate of up to 40 percent and by providing that test results may fall within a confidence band that narrows as the number of individual engines tested increases. 40 C.F.R. pt. 86, subpt. K & Table X.

[33] N.Y. Comp. Codes R. & Regs. tit 10, § 5-6.10.

[34] N.Y. Comp. Codes R. & Regs. tit. 1, § 221.11 (adopting by reference NIST Handbook 133).

[35] NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, HANDBOOK 133: CHECKING THE NET CONTENTS OF PACKAGED GOODS 4 & tbl. 2-1 (4th ed. 2002).

[36] *See* UNDERWRITERS LABORATORIES, INC, STANDARD 723: TEST FOR SURFACE BURNING CHARACTERISTICS OF BUILDING MATERIALS § 7.2 (1996) (permitting averaging of multiple test data).

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is the best way to express an IP performance standard because of the significant variability of the test method as well as the substantial variability of manufactured cigarettes.

Because the performance standard necessarily will be enforced based on highly variable test results, the standard should provide manufacturers with adequate time to perform a sufficient number of test trials (if possible, over different production lots or runs) to verify compliance. That is, because of the substantial expected variability in test results and in production, it will take a fairly large number of test trials for a manufacturer to draw conclusions regarding the IP performance of their cigarettes as they are currently designed. This uncertainty is particularly significant, given that manufacturers will have to redesign most cigarette brand styles to comply with the standard and thus test data for many brand styles will not be available prior to the effective date of the performance standard. Similarly, given the variability of certain production inputs, such as tobacco leaf and cigarette paper (banded or unbanded), PM USA anticipates that manufacturers might need to make similar minor design adjustments over time to maintain compliance with the standard.

In all of these respects, an IP performance standard will be most effective if it is based on the mean IP of cigarettes produced over time and tested using a mandatory minimum number of test trials.

PM USA proposes that OFPC require each manufacturer to demonstrate compliance with a three-year running cumulative mean performance standard through an ongoing testing program that meets the following general requirements and performance measures. With respect to each brand style of cigarette (or IP group, if permitted by OFPC), each manufacturer should be required to:

- Perform a minimum of 24 randomized test trials each year;
- Produce a cumulative test mean over the first year of production within or below a specified band of 25 ±8 PFLB;
- Produce a cumulative test mean over the first two years of production within or below a specified (but narrower) band of 25 ±3 PFLB;
- Produce a cumulative test mean over the first three years of production of no more than 25 PFLB; and
- Produce, with respect to each subsequent year, a cumulative test mean over the most recent three years of production of no more than 25 PFLB.

Under such an approach, any cigarette brand style (or IP group) that complies with the standard by producing a cumulative test mean of more than 25 PFLB but within the permitted bands during the first two years would have to be redesigned to perform at less than 25 PFLB over the final year in order to satisfy the required three-year cumulative test mean of no more than 25 PFLB. For example, any cigarette (or IP group)

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that produces a test mean of 30 PFLB in the first year and 25 PFLB in the second year would have to produce a test mean of no more than 20 PFLB in year three to bring its three-year cumulative test mean down to no more than 25 PFLB. Thus, manufacturers would have no incentive to "take advantage" of the permissible ranges in the first two years. Rather, the purpose of these bands for this limited phase-in period is to provide manufacturers with the time necessary to develop sufficient test data (over different production lots and runs) so they can determine whether further minor design changes might be necessary in order to maintain compliance with the performance standard.

4. OFPC could independently verify compliance with this performance standard.

So that the State has the capability to verify that each manufacturer has achieved and maintained compliance with the performance standard, PM USA proposes that each manufacturer be required to:

- Submit a testing plan to OFPC for its approval prior to the effective date of the standard;
- Receive OFPC approval before making any changes to its approved testing plan; and
- Provide OFPC with a replicate sample of all cigarettes randomly tested as part of the above-described OFPC-approved testing plan so OFPC can perform its own independent testing.

5. To meet a mean 25 PFLB standard, PM USA would have to substantially reduce the IP of nearly all its brands.

Achieving a cumulative mean 25 PFLB on the NIST Test (10 layers of filter paper) for all cigarette brand styles will be a significant challenge for PM USA. Nevertheless, PM USA is willing to commit the effort required to achieve compliance with this stringent but workable standard.

As discussed *supra* at 4, OFPC expressed an intent to set the performance standard based on the actual test performance of commercial cigarettes with reduced IP. To date, PM USA has introduced reduced IP technology in the Merit brand family.[37]

Among the brand styles in the Merit brand family, Merit Lights brand styles best represent the IP characteristics of the full range of cigarette brand styles consumed in New York. The IP characteristics of PM USA's Merit Lights brand styles generally are similar (though not necessarily identical) to the IP characteristics of all "Full Flavor" and

[37] PM USA's Merit brand family includes 15 different brand styles sold within the United States. Those 15 brand styles fall within two different tar ranges -- Lights (7 to 14 mg tar) and Ultralights (less than 7 mg tar). Thus, PM USA does not market any Merit brand styles that fall within the Full Flavor (15 mg and above) tar range.

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"Lights" cigarettes.[38] "Light" and "Full Flavor" cigarette brand styles produced by PM USA and other manufacturers together account for roughly 87% of all sales in the United States as well as in New York.[39] Thus, among PM USA's cigarettes currently on the market, we believe the Merit Lights brand styles represent the best benchmark candidate for an IP performance standard.

Based on test results to date, as exhibited in Appendix C to these comments, PM USA's Merit Lights brand styles have a cumulative test mean above 25 PFLB. PM USA has conducted the NIST Test (on 10 layers of filter paper) on 2,256 of its Merit Lights cigarettes -- an amount equivalent to somewhat more than 56 test trials of 40 cigarettes each. These test results have a cumulative testing mean of 28.1 PFLB. Thus, PM USA would have to modify the design of its Merit Lights cigarettes to further reduce their IP in order to comply with the mean 25 PFLB performance standard on the NIST Test proposed in these comments.

Further, because of certain differences in tobacco blends, it will be an even greater design challenge to reduce sufficiently the IP of many PM USA brand styles to achieve compliance with this standard. As also discussed *infra* at 30-32 and Appendix C to these comments, various differences in tobacco blends (in particular, different densities of the cigarette tobacco packing) are associated with differences in IP. Most significantly, the tobacco packing of Lights and Full Flavor cigarettes generally have a higher density than the packing of Ultralights.[40] Therefore, relatively speaking, because higher density packings are associated with higher IP values, it will take a more aggressive design strategy to meet the same IP standard with respect to Full-Flavor or Lights cigarettes than for Ultralight cigarettes. *See* Performance Standard Study Document at 4 (agreeing that "it may be expected that the higher tar yielding cigarettes would have higher [IP]"); *id.* at 4 (stating that "the commercially available banded cigarettes do not represent the tar yield ranges available in the marketplace or appear to be favored by purchasers in the marketplace").

Further, while Full Flavor and Lights cigarettes generally have similar tobacco densities, other differences in tobacco blends (*e.g.*, differences in tobacco types, such as Burley and Bright) also affect IP. For this reason, in order to meet the same performance standard many other Full Flavor and Lights brand styles produced by PM USA will

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[38] While "Full Flavor" brand styles deliver higher "tar" yields than "Lights," this difference in "tar" yields is not attributable to different tobacco densities. This is because the tobacco packings for "Full Flavor" and "Lights" generally contain similar amounts of expanded tobacco, and thus have similar tobacco densities. Rather, the lower "tar" deliveries from "Lights" generally result from differences in ventilation and filtration. As we explain *infra* at 30-32, while tobacco density affects IP performance, ventilation and filtration techniques do not.

[39] "Ultralights" account for the remaining 13%. PM USA's STARS database, 12-month period ending Feb. 3, 2003.

[40] Because they are made with greater amounts of expanded tobacco, Ultralight cigarettes generally have lower tobacco densities than higher-tar cigarettes. This difference in densities is associated both with lower tar delivery as well as reduced IP values.

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require even more aggressive IP-reduction design strategies than those applied to Merit Lights.

Thus, compliance with PM USA's proposed performance standard would require further advances in IP-reduction technology than have been applied to date to PM USA's Merit Lights.

* * *

In accordance with the above comments, PM USA suggests that Section 4 of the Proposed Regulation be amended to read as follows:

> "4. Performance Standard.
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> "Cigarettes sold or intended for sale one hundred eighty days after the fire safety standards stated in this regulation have been adopted, when tested in accordance with section 3 or section 9, shall exhibit a long-term production average of no more than 25 percent full-length burns. After the date of the first certification that is required pursuant to section 6(b), a brand style (or an ignition propensity group containing such brand style) shall comply with this performance standard only if, when tested in accordance with a testing plan that has been approved by the Office of Fire Prevention and Control under section 3(f), the brand style or ignition propensity group yields test data in accordance with the following --
>
> "(a) With respect to those cigarettes produced on or before the date that is 60 days prior to the date of the first certification that is required pursuant to section 6(b), the brand style or ignition propensity group shall yield a cumulative test mean of no more than 25 percent full-length burns plus or minus 8 percent full-length burns;
>
> "(b) With respect to those cigarettes produced on or before the date that is 60 days prior to the date of the second certification required pursuant to section 6(b), the brand style or ignition propensity group shall yield a cumulative test mean of no more than 25 percent full-length burns plus or minus 3 percent full-length burns;
>
> "(c) With respect to those cigarettes produced on or before the date that is 60 days prior to the date of the third certification required pursuant to section 6(b), the brand style or ignition propensity group shall yield a cumulative test mean of no more than 25 percent full-length burns; and

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"(d) With respect to those cigarettes produced during the three-year period ending on the date that is 60 days prior to the date of the fourth and each subsequent certification that is required pursuant to section 6(b), the brand style or ignition propensity group shall yield a cumulative test mean of no more than 25 percent full-length burns."

B. PM USA Believes OFPC's Proposed Performance Standard Would Not Advance the Purpose of the Legislation and Would Lead to Serious Unintended Consequences.

The standard proposed by OFPC would, in PM USA's view, be unworkable given real-world circumstances and lead to self-defeating consequences. PM USA urges OFPC to consider carefully the potential for unintended consequences should it mandate a performance standard less than a mean 25 PFLB on the NIST Test.

As discussed in more detail below, cigarettes designed to meet such a standard would have to be subjected to toxicological testing and evaluation and are more likely to be rejected by adult smokers, who would purchase non-IP-compliant products intended for distribution outside New York.[41]

Although the standard supported by PM USA also could present the same types of risk related to contraband sales, it would likely result in fewer adult smokers switching to cross-border or bootleg sources of non-IP-compliant cigarettes. This is because cigarettes that comply with PM USA's proposed standard would, it believes, be rejected by fewer adult smokers than would cigarettes made to comply with the standard proposed by OFPC. For this reason, PM USA's proposed standard would be less likely to contribute to consumer demand for non-IP-compliant cigarettes. If so, the adoption of PM USA's proposed standard would advance more effectively the purpose of the legislation without further increasing losses in state and local tax revenues.

1. The Proposed Regulation puts forward a performance standard that would require a cumulative test mean substantially less than 25 PFLB.

The most natural, literal interpretation (perhaps unintended) of the Proposed Regulation is that no cigarette may be sold in New York after the effective date if the test result on any ***single*** test trial of 40 cigarettes exceeds 25 PFLB.[42] Under such an

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[41] Consumers expect cigarettes to stay lit while being held by the smoker. A cigarette that does not remain lit could be perceived by adult smokers as a fundamentally different product.

[42] *See* Proposed Regulation § 4 (performance standard expressed as no more than 25 PFLB "of the cigarettes tested in a test trial); § 3(c) (defining a "test trial" as "forty replicate tests"); § 3(a) (referencing the ASTM Test, for which a "test" involves a single cigarette); *see* ASTM Test at 4. ("Summary of Test Method").

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interpretation, the 25 PFLB standard would operate as a "ceiling" and, given the expected variability of test results, manufacturers most likely would have to design their cigarettes to achieve a mean of about 5 PFLB on the NIST Test and perhaps even less on the ASTM Test to meet this standard. Indeed, OFPC has acknowledged that "[a]t an [IP] level much below 25% the manufacturer has to produce cigarettes that consistently give essentially zero full-length burns on 10 layers of filter paper in order to achieve compliance for any random sample of 40 cigarettes." Proposed Regulation Study Document at 8.

Apart from the serious compliance issues discussed below, PM USA agrees with OFPC that a performance standard that results in a "design to zero" strategy for compliance -- such as a single test trial "ceiling" of 25 PFLB -- would "greatly constrain[] the usefulness of the test method output and would [present] significant quality control problem[s] for the industry." *Id.*

New York's own test results show that if the 25 PFLB standard were imposed as a ceiling, at least six, and perhaps all, of the eight Merit banded paper cigarette brand styles tested by OFPC would fail to meet the standard. OFPC tested eight different brand styles of Merit banded cigarettes on the NIST Test. New York's own test trials yielded PFLB results of 45, 45, 58, 73, 75 & 83 for six different Merit Brand styles -- results which are well above 25. *See* OFPC, "Production Test Results for the 1st 100 Cigarette Packing Types," Kidde-Fenwal Inc. Combustion Research Center (the "Test Results Document") (listing results of one test trial of 40 cigarettes on each of these brands on a 10-layer filter paper substrate). As discussed *supra* at 7 and in Appendix A, PM USA would expect even higher PFLB results in single test trials involving the ASTM Test that is part of OFPC's proposed standard. Thus, it is likely that none of PM USA's current Merit brand styles would pass the standard proposed by OFPC.

2. The OFPC-proposed performance standard would create substantial uncertainty and could cause long delays related to assessing the toxicity of compliant cigarettes.

All potential cigarette or paper design modifications intended to meet the OFPC-proposed performance standard would have to be evaluated and deemed acceptable from a toxicological perspective -- a process that could take more than a year depending upon the magnitude of the change. In contrast, the PM USA supported standard can be met using technology that, by and large, has already been assessed and deemed acceptable by PM USA toxicologists.

PM USA has used a tiered toxicological testing approach to evaluate cigarette ingredients[43] and design changes.[44] This approach includes smoke chemistry,

[43] Patskan G., Reininghaus, W. Toxicological Evaluation of an Electrically Heated Cigarette. Part 1: Overview of Technical Concepts and Summary of Findings (submitted to The Journal of Applied Toxicology) (not yet accepted for publication).

[44] Carmines, E.L. Evaluation of the potential effects of ingredients added to cigarettes. Part 1: Cigarette design, testing approach, and review of results. Food and Chemical Toxicology. 40:77-91 (2002).

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genotoxicity assay, cytotoxicity assay and a 90-day animal inhalation study. A typical timeframe for testing and evaluation is 3-16 months. The magnitude of the product or technology change and the level of testing determine the timeframe. Overall, smoke chemistry and toxicological findings are deemed acceptable if there is no biologically relevant increase in existing assay activity and if there is no biologically relevant new activity.

When cigarettes made with the current banded paper technology were machine smoked using standard smoking conditions, results of smoke chemistry analysis, cytotoxicity testing, genotoxicity testing, and animal inhalation testing revealed only minor, inconsistent changes.[45] In addition, the new product scientific advisory board consulted by PM USA reviewed all the scientific information regarding smoke chemistry and toxicological findings and concluded that there was no meaningful difference between cigarettes made with banded paper and cigarettes made with conventional unbanded paper.

PM USA has performed several years of toxicological evaluations of cigarettes made with the current banded paper technology. This technology could be applied with minor changes to meet the performance standard proposed by PM USA (a three-year production average of 25 PFLB on the NIST test). It therefore would not be necessary for PM USA to perform substantial further toxicological evaluations in order for this banded paper technology to be applied to all of PM USA's brand styles.

In contrast, PM USA does not know whether a substantially lower standard -- such as the standard seemingly proposed by OFPC -- could be met without increasing toxicity, and it could take a significant amount of time for PM USA to perform the necessary toxicity testing and evaluation to make this assessment. Any significant modification of the current technology, or any new technology, would require a full battery of toxicity tests (approximately 16 months). Depending on the degree of the proposed design change, less significant changes would require toxicity tests taking three to nine months.

Further, if any modification or new technology resulted in the need for constant or intermittent re-lighting of the cigarettes, it would be very difficult if not impossible to machine smoke these cigarettes using government-accepted standard smoking conditions (*e.g.*, those accepted by the U.S. Federal Trade Commission and the Massachusetts Department of Health, Office of Tobacco Control). Without the ability to perform this critical part of the standard testing battery, it would be difficult and perhaps take substantially more time to evaluate these cigarettes from a toxicological perspective.

Simply stated, a significant modification of the existing technology -- as likely would be required by OFPC's proposed standard -- could require extensive toxicological

[45] Pakstan, *et al.* "Toxicological Characterization of a Novel Cigarette Paper" (poster presentation at the 39th annual Society of Toxicology Conference) (presenting results of studies designed to evaluate potential adverse changes in smoke chemistry or biological activity of reduced IP cigarettes).

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testing as well as modification of the scientific tools utilized to conduct the battery of toxicity tests.

The Fire Safety Law (in section 2(b)) recognizes that certain lower IP designs might have an impact on the toxicity of cigarettes.

> In promulgating fire safety standards for cigarettes pursuant to this section, the office of fire prevention and control, in consultation with the department of health, shall consider whether cigarettes manufactured in accordance with [NY IP performance] standards may reasonably result in increased health risks to consumers.

OFPC apparently has considered to a limited extent the impact that certain lower IP designs might have on the toxicity of cigarettes. For example, OFPC has recognized that the use of low porosity paper for all cigarettes might raise toxicity concerns:

> One of the OFPC-tested cigarettes that demonstrated low [IP] was a "niche" cigarette that did not appear to use a technology to specifically lower the [IP]. It's [sic] low [IP] response was probably due to a low porosity paper that was not banded. Using this approach for all cigarettes might raise toxicity concerns.

Performance Standard Study Document at 7.

However, nothing in the record suggests that OFPC has considered, or consulted the Department of Health with respect to, whether certain IP standards substantially below a mean 25 PFLB on the ASTM Test (such as would result from a 25 PFLB ceiling on a single test involving 40 cigarettes) could be achieved by cigarettes without raising toxicity concerns. OFPC asserts that it has consulted with the Department of Health on toxicity issues related to OFPC's proposed performance standard:

> The Department of Health has stated that cigarettes complying with the fire safety standards set forth in the proposed rule are not expected to change the inherently high health risks of smoking. This determination is based on the existing information on banded cigarettes, the only technology known to OFPC at this time to feasibly meet the performance standard stated in section 4 of the proposed rule.

RIS at 2-3. However, this statement suggests that the Department of Health was under the impression that currently marketed banded cigarettes could comply with the Proposed Rule. As discussed in detail *supra* at 20-21, based on a literal reading of the performance standard in the Proposed Rule, this does not appear to be the case. Thus, the Department of Health apparently has not considered whether cigarettes with a lower IP value than

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currently marketed banded paper cigarettes "may reasonably result in increased health risks to consumers."

3. A performance standard requiring a mean PFLB substantially less than 25, such as OFPC's proposed standard, may trigger substantial purchases of non-IP-compliant cigarettes, thus undermining the purpose of the statute.

Based upon its substantial experience with the testing and introduction of banded paper technology, PM USA expects that cigarettes complying with OFPC's proposed performance standard would go out more frequently while being smoked and be rejected by a significant number of adult smokers. This could result in substantial consumer purchases of non-IP-compliant cigarettes intended for distribution outside of New York. Such a standard therefore could have the perverse effect of achieving no improvement in the IP of the cigarettes that are actually smoked by New Yorkers. In that event, the proposed performance standard would not achieve the objective of the Fire Safety Law.

In contrast, the standard supported by PM USA -- a three-year cumulative test mean of 25 PFLB on the NIST Test -- would both result in a substantial lowering of the IP of nearly every brand in the marketplace and be less likely than the performance standard proposed by OFPC to cause as many adult smokers to increase their purchases of non-IP-compliant cigarettes. If so, the standard supported by PM USA would do more to lower the IP of cigarettes actually consumed in New York and is more consistent with OFPC's stated objectives. *See* Proposed Regulation Study Document at 6 ("Lowering the [IP] of the current cigarettes that represent the majority of the current market share is likely to limit the risk of ignition under real conditions for the population.")

Many adult smokers reported lower acceptability scores to PM USA for lower IP cigarettes, including with respect to overall subjective acceptance of the product. Perhaps most significantly, such cigarettes have higher rates of self-extinguishment *i.e.*, the cigarettes go out when being held by the smoker during smoking. Although it is desirable for cigarettes to go out when they are carelessly dropped or placed on a material that could ignite, cigarettes that self-extinguish while being smoked are annoying to adult smokers and could be perceived as having a quality problem, as being inferior or as not being made correctly.

While the level of consumer complaints related to self-extinguishment may be tolerable for cigarettes, such as Merit Lights, that have a mean PFLB in the range of 25, PM USA believes that substantially lower IP cigarettes that more frequently self-extinguish are far more likely to be rejected by adult smokers. PM USA research among adult smokers during the development stage of banded paper cigarettes showed that, as the IP level decreases, measured self-extinguishments, as well as reported incidences of self-extinguishment, increase. Consistent with this research, the level of consumer complaints received from adult smokers of Merit cigarettes increased dramatically -- by a factor of 8 -- after the national introduction of banded paper on the Merit brand family. Many Merit smokers rejected the change to banded paper. In addition to increased consumer complaints, sales of the Merit brand family decreased 19.6% in the year

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following the national introduction of banded paper on Merit in August 2000. While PM USA cannot determine precisely what portion of this decline was due to adult consumer rejection of banded paper cigarettes or to other marketplace forces -- such as price, the level of marketing support or the overall decline in cigarette consumption -- the steep rise in consumer complaints leads PM USA to believe that a significant portion of this decline was attributable to consumer rejection of banded paper cigarettes. Nevertheless, the frequency of self-extinguishment was ultimately tolerable to many adult smokers of cigarettes with an IP in the range of mean 25 PFLB, such as Merit Lights.

4. NYS and NYC tax revenues would be severely reduced by substantial further growth in the purchase of out-of-state cigarettes.

As detailed above, a standard that requires a cumulative mean substantially less than 25 PFLB is likely to drive up self-extinguishments to such an extent that many adult smokers would switch from legitimate distribution channels to readily available cross-border and bootleg sources where they can obtain non-IP-compliant cigarettes.

OFPC's standard therefore could seriously compound New York's cigarette bootlegging problem, which would trigger a tremendous loss in cigarette excise tax revenues for New York State and New York City and impose substantial costs on the thousands of licensed New York cigarette retailers, wholesalers and vending machine operators.

a. Tax-motivated purchases of cigarettes intended for distribution outside New York already are a serious problem in New York State (including New York City).

PM USA is working actively with New York law enforcement officials and others to combat the unlawful sale of contraband cigarettes. While PM USA cannot enforce State or City revenue laws, it has taken a variety of steps to address the issue of illegal contraband sales in or into New York. For example, PM USA supports legislation that would tighten New York's cigarette distribution rules to make it easier for the state to prevent contraband sales. PM USA also has sent "cease and desist" letters to Internet sites and other sellers found to be selling illegally imported product or misusing PM USA's trademarks. Additionally, PM USA has supported litigation filed by New York City against various websites selling contraband cigarettes, and refused to join the lawsuit brought by other cigarette manufacturers challenging the state statute enacted to prevent Internet sales.

Nevertheless, New York's experience with tax-motivated purchases of cigarettes intended for sale and distribution outside New York demonstrates that adult smokers in New York will be able to find numerous outlets through which they might purchase non-IP-compliant cigarettes if they want to do so. Sources of non-IP-compliant cigarettes

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include: (1) cross state border purchases;[46] (2) mail, telephone and Internet orders from out-of-state or non-U.S. sources;[47] (3) sales on or from Native American reservations located in New York;[48] and (4) street sales or sales from non-compliant retail outlets.[49]

The substantial evidence that New York adult smokers already have ready access to cigarettes not intended for sale or distribution in New York and that many adult smokers already purchase from these sources includes the following:

- A 1998 study by the Tax Foundation estimated that, in a substantially lower tax environment, 15.7% of cigarettes consumed in New York State enter the state

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[46] The New York Fire Safety Law does not prohibit New York consumers from traveling out of the state to purchase non-IP-compliant cigarettes, nor does it prohibit such consumers from bringing those cigarettes back into New York for consumption.

[47] The Fire Safety Law and/or New York law related to the licensing of dealers would prohibit such out-of-state delivery sales to consumers in New York of cigarettes that do not comply with the standard. However, the fact that such sales would be illegal does not necessarily mean they would not still occur. For example, Internet cigarette sales have grown substantially in recent years notwithstanding that in most cases such sales are being made in violation of the federal Jenkins Act (15 U.S.C. §§ 375-378). *See* U.S. General Accounting Office, Pub. No. 02-743, *Internet Cigarette Sales: Giving ATF Investigative Authority May Improve Reporting and Enforcement* 16 (2002) (hereinafter "GAO Report") ("Most Internet Cigarette Vendors Do Not Comply with the Jenkins Act."). In February 2003, the Second Circuit Court of Appeals upheld N.Y. Public Health Law § 1399-*ll*, which prohibits Internet, mail-order or any other sellers from shipping cigarettes directly to New York consumers. *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200 (2d Cir. 2003). The statute has exceptions and its effectiveness remains to be seen.

[48] Native American tribes in New York reportedly sell cigarettes at reservation stores without collecting the applicable taxes from non-tribal purchasers. *See* Hope Reeves, *Read Their Lips: No Taxes. (Period.); Smokers Flocking to Reservations to Buy Cigarettes, Cheap*, N.Y. Times, July 8, 2002, at B1. New York previously adopted regulations that would have provided a method to collect taxes on reservation sales, but the regulations were repealed after riots and civil disobedience by Native American tribes. *See* Karen L. Folster, *Just Cheap Butts, Or An Equal Protection Violation?: New York's Failure to Tax Reservation Sales to Non-Indians*, 62 ALB. L. REV. 697, 707–08 (1998). Since then, New York effectively has engaged in a policy of non-enforcement of the tax laws for reservation sales. *See N.Y. Ass'n of Convenience Stores v. Urbach*, 694 N.Y.S.2d 885, 889 (Sup. Ct. Albany County 1999) (discussing history of New York's non-enforcement for reservation sales), *aff'd*, 275 A.D.2d 520 (3d Dep't 2000).

[49] Gordon Fairclough, *Psst! Wanna Cheap Smoke? Big Tax Rise in New York City Fuels Thriving Black Market in Illegal, Low-Tax Cigarettes*, Wall St. J., Dec. 27, 2002, at B1 (indicating that "trafficking in cigarettes has exploded in recent months.... Bootleggers sell untaxed cigarettes from car trunks; cab drivers offer them to passengers; and corner groceries sell them to favored customers"); William Sherman, *$200 M Lost to Smokes Smugglers Yearly City, State Tax Shortfall From Gang & Internet Sales*, N.Y. Daily News, Sept. 23, 2002, at 5 (reporting that tax enforcement agents seized untaxed cigarettes during raids of three stores in a four-block area in Brooklyn); Brendan Lyons, *Man Accused of Sales of Bootleg Cigarettes*, Times Union, Oct. 30, 2002, at B5 (reporting that a man is facing felony charges for allegedly selling bootleg cigarettes at the local YMCA where he works); Al Guart, *Burning Issues Steam the Apple – Butt-Leggers' Sell Illicit Cigs Under Cops' Noses*, N.Y. Post, Aug. 18, 2002, at 9 (reporting on the presence of illegal vendors at numerous locations across the city); Yancey Roy, *Sales of Cigarettes Lag Following New York Tax Hike*, Star-Gazette, Nov. 23, 2002, at 1C (reporting on two men selling approximately 600 cartons of illegal cigarettes from gas stations).

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through smuggling and 18.4% enter through cross-border sales.[50] Subsequent increases in the difference in the tax rates between New York and other sources probably have further increased the percentage of New York adult smokers who obtain their cigarettes from non-New York sources.

- In 2001, an estimated 37 to 42 million cartons of cigarettes were brought into New York but not taxed,[51] including 27 million cartons sold by alternate distribution channels (Internet, 800-number phone networks and Native American sales), contraband sales of 7-10 million cartons and cross-border activity of 3-5 million cartons. PM USA estimates that 2001 total industry sales in New York other than sales to Native Americans were about 85 million cartons. Thus, sales through these non-taxed avenues during this period were estimated to be almost half as large as taxable sales.

- PM USA estimates that 46% of the New York State population lives 10 miles or less and 59% live 20 miles or less from the border with a neighboring state.

- Survey results show that, among all adult smokers in New York, awareness that cigarettes can be purchased over the Internet has risen from 24.7% in three months ending March 2000, to 67.8% the three months ending November 2002.[52]

- According to a New York City Department of Finance press release from April 16, 2002, which was based on experience prior to the 2002 tax rate increase: "Cigarette tax evasion costs the City an estimated $40 million in lost tax revenue annually."[53]

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[50] Patrick Fleenor, "How Excise Tax Differentials Affect Interstate Smuggling and Cross-Border Sales of Cigarettes in the United States," Tax Foundation Background Paper No. 26, October 1998, p. 11. During the 1997 period examined in the Tax Foundation study, the New York State cigarette excise tax was $0.56 per pack, and the New York City cigarette excise tax was $0.08 per pack. During 2002, each of these taxes was raised to $1.50 per pack, thus resulting in a total excise tax today of $3.00 per pack in New York City.

[51] Ridgewood Economic Associates, Ltd., "New Cigarette Tax Revenue Sources for New York State," prepared for the FACT Alliance for the Fair Application of Cigarette Taxes, December 24, 2002. This figure does not include an estimated 6-8 million packs brought into New York State but sold by Internet and 800 numbers outside the state.

[52] Continuous Adult Smoker Tracking Study ("CASTS"). CASTS is a proprietary PM USA study based on random digit dialing telephone surveys conducted daily.

[53] "Commissioner Martha E. Stark Announces Successful Crackdown on Cigarette Smugglers and Retailers," New York City Department of Finance, April 16, 2002, at. 1.

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b. Consumer reaction to brand styles meeting a standard substantially less than a mean of 25 PFLB can be expected to seriously compound New York's cigarette bootlegging problem.

As discussed *supra* at 24-25, under a performance standard substantially below PM USA's proposed standard, New York adult smokers can be expected to find unacceptable the characteristics of those brand styles that are available for sale in New York through legitimate distribution channels. As a result, a substantial number of adult smokers can be expected to seek out non-IP-compliant cigarettes intended for sale and distribution outside of New York.

The evidence presented above shows that a large percentage of New York adult smokers already acquire their cigarettes from cross-border shipments, smuggling, Native American outlets, or mail, phone or Internet orders. In large measure, these adult smokers have turned from traditional retail sources to these alternative sources for at least some of their cigarette purchases, in order to avoid higher New York cigarette taxes, which rose in 2002 to $1.50 per pack (plus, in New York City, an additional $1.50 per pack). It can be expected that these adult smokers would increase their purchases from out-of-state sources and that even more adult smokers would obtain non-IP-compliant cigarettes from out-of-state sources, if they conclude that cigarettes compliant with the IP standard have undesirable characteristics such as frequent self-extinguishments while being held.

c. NYS and NYC could suffer tremendous revenue losses.

New York State receives approximately $1 billion per year in revenues from cigarette taxes.[54] No precise estimate has been prepared of how many additional adult smokers currently purchasing cigarettes with a New York tax stamp would be motivated, under a performance standard substantially below a mean 25 PFLB standard, to turn to non-IP-compliant cigarettes without a New York tax stamp.

However, if only 10% of current consumers were to do so, the State would lose approximately $100 million in annual revenue. The lost tax revenue would be many times higher if 20%, 30% or some higher percentage of these consumers switched to non-New York State sources. These percentage switches are realistic possibilities in terms of likely switches to cross-border or bootlegged cigarettes if the standard in the Proposed

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[54] Net collections of taxes on cigarettes and tobacco products in FY 2001-2002 were $1.014 billion. See http://www.tax.state.ny.us/collections/sfy01-02/02-03_collections.htm. Cigarette and tobacco tax receipts are estimated to be $1.132 billion in FY 2002-2003 and $1.078 billion in FY 2003-2004. See *New York State 2003-2004 Executive Budget Appendix II*, pp. 185-186. http://www.budget.state.ny.us/pubs/executive/executive.html. Cigarette and tobacco tax receipts are made up predominantly of cigarette taxes. In FY 2000-2001, for instance, net collections on cigarette taxes were $1.0 billion and net tobacco collections were $20 million or 2%. New York State Department of Taxation and Finance, *2000-2001 New York State Tax Collections,* January 2002, p. 26.

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Regulation were to be adopted. The State also would lose sales tax revenues on these sales. In addition, local governments within New York State would lose sales tax revenue, and New York City would lose tobacco excise tax revenue.

Thus, the cost to New York State would be substantially greater than the amount estimated in the Proposed Regulation. In addition, contrary to the statement in the Proposed Regulation, at 5, there would be substantial costs -- and not "no costs" -- "to local governments for the implementation and continuation of the proposed rule."

d. The sale of non-IP-compliant cigarettes in NYS and NYC may also put at risk the livelihoods of thousands of tax-paying, tax-collecting state businesses including licensed tobacco retailers, wholesalers and vending machine operators.

According to its most recent annual tax filing, the state of New York now collects in excess of $3.2 million solely from the license fees it imposes on retail dealers in tobacco products in the state of New York.[55] PM USA understands that each such business must pay a $100 fee and that many such businesses fail during the year. Accordingly, the total number of tobacco retailers (of all types) in the state now stands somewhere in the range of 30,000. In addition, PM USA understands that the state separately licenses approximately 350 tobacco wholesalers. PM USA itself maintains "direct" accounts with about 100 such wholesalers who serve New York State customers. Finally, the state licenses approximately 500-600 cigarette vending machine operators. Non-IP-compliant cigarette sales by non-licensed vendors will compete with and likely reduce the legitimate tobacco sales of many of these legally registered retail outlets, wholesale dealers and vending machine operators.

For example, in its February 12, 2003 comments to OFPC, the New York Association of Convenience Stores ("NYACS") set forth, in some detail, its concerns as to the financial impact that non-IP-compliant cigarette sales may have on convenience stores in New York. NYACS represents 5000 licensed neighborhood convenience stores that serve more than 4 million customers daily. NYACS member stores employ approximately 30,000 New Yorkers.[56] For these convenience stores, tobacco products typically account for one-third or more of overall sales inside the store. Tobacco products also serve as a leading traffic generator.

NYACS states that if the standard proposed by OFPC results in cigarettes that will not stay lit or that are perceived by customers to be inferior, it will be the owners and the 30,000 New Yorkers who are employed at these 5000 stores who will bear the brunt

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[55] Net cigarette license revenues for FY 2002 were $3,233,654. See New York State Department of Taxation and Finance, *2000-2001 New York State Tax Collections,* Jan. 2003, Table 13.

[56] New York Association of Convenience Stores (NYACS) "Comments," Feb. 12, 2003.

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Source: https://www.industrydocuments.ucsf.edu/docs/gyhk0001

of consumer shifts to vendors of non-IP-compliant products.[57] In NYACS' view, many smokers may immediately and permanently abandon these outlets with consequent losses in store profits, state taxes and jobs for New Yorkers. The other 25,000 plus licensed tobacco retailers may of course be similarly affected by in-state sales of non-IP-compliant product. Moreover, there is no reason to limit the negative effects of widespread sales of non-IP-compliant products solely to the retail sector. Wholesalers who serve licensed retailers would also be affected, as would licensed operators of cigarette vending machines.

* * *

PM USA notes that the standard it proposes could present the same types of risk described above. PM USA believes, however, that cigarettes that comply with its proposed standard would be more acceptable to adult smokers and would accordingly provide less incentive for consumers to seek out non-IP-compliant cigarettes, thus avoiding the unintended consequences PM USA believes would result from adoption of the OFPC proposed standard.

IV. COMMENTS CONCERNING IMPLEMENTATION OF THE PROPOSED REGULATION.

A. OFPC Should Permit Manufacturers To Test Cigarettes in OFPC-Approved IP Groups that Have Common Performance Parameters Relevant to IP.

PM USA proposes that OFPC permit each manufacturer to submit to OFPC, for the agency's approval, an IP group plan based upon the most relevant IP performance parameters. Appendix C to these comments provides further detail with respect to the utility and purpose of IP groups. OFPC should permit IP groups to include cigarettes that are marketed under different brand names and that do not have the exact same design specifications (*e.g.*, filtration, ventilation and packaging), so long as those design differences would not be expected to have a substantial impact on IP. If an IP group plan were approved by OFPC, the cigarette brand styles in each IP group would be tested together via a representative and random sample of the cigarette brand styles in a respective IP group. This approach would prevent unnecessary testing without undesirably combining the test results of cigarette brand styles that have substantially different IP.

The Proposed Regulation incorporates the Fire Safety Law's definition of the term "cigarette" and would specify that "[f]orty replicate tests shall comprise a complete

[57] PM USA also expects that it would lose some customers as a result of the Proposed Regulation. While some adult smokers might continue to buy the New York State-regulated product, others likely would seek cigarettes from cross border or bootleg sources. PM USA expects that in this transition away from customary retail outlets, some percentage of PM USA's customer base would be lost.

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test trial for each cigarette tested."[58] OFPC would require each manufacturer to certify that "each cigarette listed in [that manufacturer's] certification" has been tested in accordance with Section 3 and meets the performance standard in Section 4.[59]

As proposed, however, the regulation does not identify how a manufacturer, in performing testing and certification, is to distinguish between its various cigarettes as they are sold in New York. Such distinction between cigarettes is important, because it directly impacts both the number of tests to be performed (including both the consequent demand for limited laboratory resources available to all manufacturers and the State and the costs of conducting the tests) and the ultimate determination of whether a manufacturer's cigarettes are in compliance.

PM USA estimates that sales of its products in New York include approximately 240 unique cigarette "brand styles".[60] However, a large number of these cigarette brand styles are substantially the same, if not identical, to other brand styles for purposes of IP testing and performance, because most of the eight factors are of minor relevance or are not relevant at all (*e.g.*, package description) to IP.

In this respect, a few performance parameters typically affect a cigarette's IP: tobacco packing density and tobacco blend components, cigarette circumference, paper permeability and/or the use of IP-reduction technology.[61] Packing density, circumference and paper permeability all are measurable, and quantitative distinctions or gradations can be made for each of these design parameters. Further, the number of different types of tobacco blends is substantially smaller than the number of cigarette brand styles. Similarly, IP reduction technology either will be the same, substantially the same, or significantly different with respect to how that technology is applied to each respective brand style.

As a result, discrete IP groups of cigarette brand styles can be created to reflect ranges in these parameters. Using this approach, PM USA estimates that it could identify in the range of 30-100 such IP groups for the PM USA cigarettes that are sold in New

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[58] Sections 2(b) & 3(c).

[59] Section 6(a).

[60] Each cigarette listed in the proposed certification would have to be described (in the certification) with eight pieces of information (*e.g.*, brand, packing or style, length). *See* Section 6(b). All but the last of these eight factors (*i.e.* "marking approved in accordance with [S]ection 8 of [the fire safety regulation]") can be used to differentiate cigarette brand styles.

[61] Research pursuant to the federal Cigarette Safety Act of 1984 (P.L. 98-567) showed that modifications to packing density, cigarette circumference and paper permeability could reduce the likelihood that a cigarette would start a fire on a substrate such as upholstered furniture or similar home furnishings. RICHARD G. GANN ET AL., TECHNICAL STUDY GROUP ON CIGARETTE AND LITTLE CIGAR FIRE SAFETY, NAT'L BUREAU OF STANDARDS, THE EFFECT OF CIGARETTE CHARACTERISTICS ON THE IGNITION OF SOFT FURNISHINGS 89 (1987).

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York. All of the cigarettes in any one IP group would share common IP characteristics and would be expected to result in substantially similar IP test values.

To help ensure that manufacturers use appropriate and consistent criteria in selecting their cigarettes for testing and that manufacturers have clear direction as to their obligations (and discretion) in this regard, the final regulation should address the manner in which cigarettes may be placed into IP groups. Thus, a provision should be included in the final regulation which (a) states that tobacco packing density and tobacco blend components, cigarette circumference, paper permeability, and/or any IP-reduction technologies are the performance parameters of most relevance to IP; and (b) authorizes manufacturers to (i) test their cigarettes in IP groups based upon these criteria, and (ii) base their certifications upon such test results. In particular, PM USA recommends that each manufacturer be allowed to submit, for OFPC's review and approval, proposed IP groups, including the rationale for such groups. Regulatory language could be included which facilitates discussions between OFPC and a manufacturer concerning the manufacturer's proposed IP group plan and the rationale therefor,[62] and OFPC would retain the authority to modify the IP groups in light of new information or knowledge about IP testing and/or the manufacturer's cigarette products.

B. OFPC Should Require Each Manufacturer to Conduct a Minimum Number of Test Trials per IP Group per Year Pursuant to an OFPC-Approved Testing Plan.

PM USA proposes that OFPC require each manufacturer to conduct a minimum of 24 test trials per year for each of its OFPC-approved IP groups.[63] A minimum of 24 trials per year per IP group would ensure that OFPC would be able to have confidence in the statistical significance of the manufacturer's cumulative test results. Further, OFPC should require each manufacturer to submit, for OFPC's review and approval, a proposed test sampling protocol. Such protocol could be submitted jointly with the manufacturer's proposed IP group plan.[64]

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[62] PM USA anticipates that, with respect to certain information that might be included in such an IP group plan, it might be necessary to seek protection for certain trade secret and other confidential information as afforded by Public Officers Law, § 87(2)(d).

[63] In the absence of IP groups, *i.e.* if PM USA were required to separately test each of its approximately 240 cigarette brand styles, a substantially lower number of test trials per brand style should be required.

[64] Other testing matters that might merit attention in the final regulation, in part because they could impact certifications, include chain-of-custody procedures and the retention (*e.g.* three years) of test replicates.

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C. OFPC Should Conform the Certification Requirements To Reflect the Standard Proposed by PM USA.

The Proposed Regulation contains the following provisions to implement the certification provisions of the Fire Safety Law:[65] (1) each manufacturer must submit a certification attesting that, for each cigarette listed in the certification, the cigarette "has been tested in accordance with section 3 of [the regulation]" and "meets the performance standard set forth in section 4 of [the regulation]";[66] (2) each cigarette listed in a manufacturer's certification must be described with eight items of information (*e.g.*, brand, packing or style, length);[67] (3) each cigarette must be recertified every three years, and a manufacturer's test data must be kept on file for three years (and provided to OFPC and the Attorney General upon request);[68] and (4) cigarettes that have been certified in accordance with Section 6 must be marked to indicate their compliance with the regulation.[69]

Once the regulation is effective: (1) no cigarette may be sold (or offered for sale) in the State unless the manufacturer has filed the written certification for that cigarette with OFPC and the Office of the Attorney General;[70] and (2) each manufacturer must provide a copy of its certifications to all of its wholesale dealers and agents, who must provide copies of all such certifications to all of their retail dealers.[71]

These provisions should be supplemented in certain respects when incorporated in a final regulation.

- OFPC should require each manufacturer to file separate certifications with the State for each of its cigarette brand styles or IP groups. However, to minimize confusion in the cigarette distribution chain, OFPC should require each manufacturer to file only

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[65] With respect to certifications, the Fire Safety Law states that, once OFPC's fire safety standards (*i.e.* the Proposed Regulations) take effect: (1) "no cigarettes shall be sold or offered for sale in this state unless the manufacturer thereof has certified in writing to [OFPC] and the attorney general that such cigarettes meet the performance standards prescribed by [OFPC] . . . ."; (2) manufacturers must provide copies of their written certifications to wholesale dealers and agents, and OFPC must prescribe procedures for retailers to be notified of all cigarettes that have been certified; (3) any wholesaler or retail dealer who knowingly sells cigarettes that have not been certified is subject to civil penalties; and (4) any manufacturer that knowingly makes a false certification also is subject to civil penalties. N.Y. Fire Safety Law §§ 3-5. Also, the Attorney General is authorized to bring actions to recover civil penalties and to enjoin acts that violate the Fire Safety Law. *Id.* at § 6.

[66] Sections 6(a)(1)&(2).

[67] Section 6(b).

[68] Sections 6(c) & 5.

[69] Section 8.

[70] Section 1(c).

[71] Section 7 (wholesale dealers, agents and retail dealers also must retain copies of all certifications for a period of three years and must permit OFPC representatives to inspect copies of such certifications).

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one combined certification with each of its wholesale dealers and agents, which should list each of the manufacturer's brand styles that are covered by a certification that has been filed with the State.

- In general, compliance with the certification requirements should be determined based upon the manufacturer's actual testing data. That is, each manufacturer should be required to certify annually that each brand style or IP group of its cigarettes has been tested in accordance with its OFPC-approved testing plan and that the resulting test data comply with the required performance measures provided in the performance standard.

- In addition to this retrospective certification of test data, OFPC should require each manufacturer to prospectively certify its good faith belief, supported by reasonable evidence and test results, that its cigarette brand styles will continue to comply with the performance standard in the coming year.[72]

- PM USA does not believe that manufacturers will be able to generate sufficient test data to certify every newly-redesigned cigarette brand style by the time the final standard takes effect. Thus, PM USA proposes that the initial certification should be prospective only. Of course, each initial prospective certification would be followed by the year-end retrospective certification, which would report whether each brand style that was included in the initial prospective certification did in fact comply with the standard.

- OFPC should specify the dates when certifications must be filed with OPFC and the Attorney General's office, as well as the production period to be covered by the certifications. To provide for adequate time to conduct IP testing, these dates should allow for a reasonable lag time between the end of the covered production period and the date of certification. OFPC also should provide a mechanism for certification of new products during the course of the year, as well as a process for seeking OFPC-approval of any necessary changes in the OFPC-approved testing plan.

PM USA suggests that the certification and related provisions of the Proposed Regulation be amended to read as follows:

> "Section 1. General Requirements.
>
> "One hundred eighty days after the fire safety standards stated in this regulation have been adopted, no cigarettes subject to the provisions of section 156-c of the executive law shall be sold or offered for sale in this state unless a written certification has been filed by the manufacturer

[72] This approach is modeled after the certification provisions of the Consumer Product Safety Act. *See* 15 U.S.C. § 2063.

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with the Department of State Office of Fire Prevention and Control, 41 State Street, Albany, New York, 12231-0001, and the Office of the Attorney General, Attn: Assistant Attorney General in Charge, Legislative Bureau, State Capitol Building, Albany, New York 12224-0341 in accordance with section 6 of this Part."

* * *

"6. Certification.

"(a) On or prior to the effective date of the performance standard, each manufacturer shall submit in writing to the Office of Fire Prevention and Control a certification that its cigarettes, itemized by brand style and ignition propensity group, meet the performance standard. For purposes of this certification only, such cigarettes shall be deemed to meet the performance standard if the manufacturer attests that:

"(1) Each brand style listed in the certification will be tested in accordance with a testing plan that has been approved by the Office of Fire Prevention and Control under section 3(f) of this Part; and

"(2) The manufacturer has a good-faith belief, supported by reasonable evidence and available test results, that the test results for each brand style or ignition propensity group (produced under the testing plan) will confirm compliance with the performance standard.

"(b) Each year, on the same day and month on which the performance standard became effective, each manufacturer shall submit in writing to the Office of Fire Prevention and Control a certification that its cigarettes, itemized by brand style and ignition propensity group, meet the performance standard. For purposes of this certification only, such cigarettes shall be deemed to meet the performance standard if the manufacturer attests that:

"(1) Each brand style listed in the certification has been and will continue to be tested in accordance with a testing plan that has been approved by the Office of Fire Prevention and Control under section 3(f) of this Part;

"(2) The manufacturer's test results for each brand style or ignition propensity group (produced under the testing plan), as of the date that is 60 days prior to the date of such

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certification, demonstrate compliance with the performance standard; and

"(3) The manufacturer has a good-faith belief, supported by reasonable evidence and test results, that the future test results for each brand style or ignition propensity group (produced under the testing plan) will continue to demonstrate compliance with the performance standard."

"(c) Each brand style listed in the certifications required by subsections (a) and (b) of this section shall be described with the following information:

"1. brand (*i.e.*, the trade name on the package)

"2. "tar" descriptor (*e.g.*, light, ultra light)

"3. length in millimeters

"4. circumference in millimeters

"5. flavor (*e.g.*, menthol) if applicable

"6. filter or non-filter

"7. package description (*e.g.*, soft pack, box)

"8. marking approved in accordance with section 8 of this Part."

"(d) Manufacturers may submit an amended certification during the course of the year to address any new brand styles or other necessary changes in its certification. Any certification with respect to a new brand style may be made under the provisions of subsection (a)."

* * *

"7. Notification of Certification.

"(a) Beginning on the date on which the performance standard adopted under section 4 becomes effective, and every three years thereafter, manufacturers certifying cigarettes in accordance with section 6 shall provide a notification of certification to all wholesale dealers and agents to which they sell cigarettes. Such notifications of certification shall list each of the manufacturer's brand

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styles that are listed in the certification that has been filed with the Office of Fire Prevention and Control.

"(b) Wholesale dealers and agents shall provide a copy of all notifications of certification received from manufacturers to all retail dealers to which they sell cigarettes. Wholesale dealers, agents, and retail dealers shall retain copies of all notifications of certifications received for a period of three years. Wholesale dealers, agents, and retail dealers shall permit the Office of Fire Prevention and Control to inspect copies of notifications of certification received in accordance with this section, and to inspect markings of cigarette packaging in accordance with section 8 of this Part.

"(c) Each manufacturer shall provide, within 30 days of filing any relevant certification with the Office of Fire Prevention and Control, an amended notification of certification to all wholesale dealers and agents to which they sell cigarettes to reflect:

"(1) any brand styles that were not listed in the most recent notification of certification and that are listed in the certification filed with the Office of Fire Prevention and Control; or

"(2) any brand styles that were listed in the most recent notification of certification and that are not listed in the certification filed with the Office of Fire Prevention and Control.

D. OFPC Should Clarify Certain Matters that Are Relevant to Determining Manufacturers' Compliance with the Regulation's Performance Standard.

If OFPC chooses to test the replicate cigarettes that must be provided to it by the manufacturer to determine whether a particular cigarette brand style or IP group complies with the regulation's performance standard, such testing should conform to Section 3 and other regulatory requirements. For example, such testing should adhere to the same testing requirements related to: (1) sample sizes and protocols (*e.g.*, all of the replicate samples for the relevant time period provided by the manufacturer to OFPC should be tested); (2) laboratory quality control and quality assurance programs.

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Further, in general, any finding of non-compliance by OFPC[73] should apply only to the relevant cigarette brand style or, as applicable, the relevant IP group.

PM USA suggests that the following section be added to the Proposed Regulation to address such independent testing by OFPC:

> 9. Compliance Testing by Office of Fire Prevention and Control.
>
> "(a) The Office of Fire Prevention and Control may conduct independent testing to determine whether a brand style certified in accordance with section 6 complies with the performance standard set forth in section 4. Such compliance testing shall be conducted in accordance with the test method established in section 3 and the testing plan for such brand style approved by the Office of Fire Prevention and Control pursuant to section 3(f), and shall be conducted only on the entire sample provided by the manufacturer in accordance with subsection(c) with respect to the compliance years in question.
>
> "(b) Each manufacturer shall retain replicate samples of each brand style that is listed in a certification. Such replicate samples shall be drawn in accordance with the approved testing plan and shall be provided by the manufacturer upon request to the Office of Fire Prevention and Control for purposes of the compliance testing authorized by subsection (a) of this section.
>
> "(c) If the Office of Fire Prevention and Control determines, pursuant to testing conducted in accordance with subsection (a) of this section, that a brand style or ignition propensity group does not comply with the performance standard set forth in section 4 of this Part, such determination shall apply only with respect to the particular brand style or ignition propensity group found to be non-compliant."

[73] Wholesalers and retailers should not bear the burden of any confusion that may result from disparate replication testing by OFPC. In other words, a manufacturer's certification should be deemed reliable for purposes of compliance with Executive Law § 156-c(5)(a), absent a final and enforceable determination that such certification is erroneous and notification of this determination to wholesalers and retailers.

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E. The Proposed Marking Requirements Appear To Be Workable.

Section 8 of the Proposed Regulation specifies requirements for marking cigarette packings in order to indicate compliance with the regulation. These requirements include a procedure for each manufacturer to obtain OFPC's approval to mark all of that manufacturer's cigarettes (as sold in New York) according to one of three methods.

The proposed requirements appear to be workable, although PM USA suggests that they be modified in one respect. That is, proposed Section 8(e) states that a manufacturer's proposed method will be deemed approved by OFPC if the State Fire Administrator fails to act within 10 business days after receiving the manufacturer's proposal. Similar "default" language should be included in Section 8(f) concerning a manufacturer's proposal to modify its previously approved method.

F. The Standard Should Take Account of Compliance Measures for Non-Conventional Cigarettes That Do Not Burn Down.

The Proposed Regulation (in Section 2(b)) incorporates the Fire Safety Law's definition of "cigarette":

> any roll for smoking whether made wholly or in part of tobacco or any other substance, irrespective of size or shape and whether or not such tobacco or substance is flavored, adulterated or mixed with any other ingredient, the wrapper or cover of which is made of paper or any other substance or material except tobacco.

PM USA is aware of at least one product that is commercially available in limited markets -- its Accord cigarette designed to be smoked exclusively in its Accord Puff-Activated Lighter™. The Accord cigarette does not burn down the rod like conventional cigarettes and is not lit with an open flame or conventional electric lighter. Rather, the Accord cigarette is heated within PM USA's unique Puff-Activated Lighter™. Thus, the Accord electrically heated cigarette would appear to fall within the Proposed Regulation's proposed definition of "cigarette", even though this particular cigarette does not exhibit IP of the type or magnitude of conventional cigarettes.

PM USA recommends that the final regulation include the following language – modeled after a similar provision in the Joseph Moakley Memorial Fire Safe Cigarette Act now pending before the U.S. Congress – to address the Accord electrically heated cigarette and other unique or non-traditional products that may be introduced into New York State:

> "With respect to any cigarette that cannot be tested using the testing methodology referred to in Section 3 because of unique or nontraditional characteristics, OFPC shall accept a testing methodology and performance standard that are

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proposed by the manufacturer or manufacturers of the cigarette if OFPC, after review of the application of the proposed testing methodology and performance standard, determines that the cigarette has an ignition propensity equivalent to or less than cigarettes that meet the performance standard in Section 4."

G. OFPC Should Address the Significant Costs and Disruption that Could Be Associated with Returns of Non-IP-compliant Cigarettes After the Effective Date of the Standard.

Under the Proposed Regulation, New York cigarette agents, as well as wholesale and retail dealers, will no longer be permitted to sell or distribute non-IP-compliant cigarettes in New York as of the effective date of the standard. Thus, as of the effective date, there may be a substantial supply of non-IP-compliant cigarettes at various points in the distribution pipeline.

If New York wholesale and retail dealers are required to empty their shelves of all non-IP-compliant cigarettes as of the effective date of the Regulation, there is a risk that this would trigger substantial costs for New York's approximately 30,000 retail dealers, 309 wholesale dealers and 116 cigarette stamping agents.[74] A substantial percentage of these agents and dealers are small businesses. Their expenses would include the costs of gathering, transporting, returning and/or selling these non-IP-compliant cigarettes outside of New York. In many instances, these types of businesses do not have the space necessary for such activities.

Further, a mass of product returns would trigger an unprecedented number of applications both to New York State and New York City for the refund of cigarette excise taxes that have been paid through the tax stamps on these products that no longer would be saleable in New York. Processing the paperwork associated with these refunds could trigger substantial additional costs for the relevant agents and wholesale and retail dealers, as well as substantial costs for the City and the State. Further, such a mass of refund applications could heighten the potential for fraudulent refund applications, thereby triggering additional time and cost for the State and City in processing these applications.

Given the potential for such substantial transition costs, PM USA urges OFPC to announce a policy of non-enforcement at the wholesale level for a period of 30 days and at the retail level for a period of 120 days following the effective date of the Regulation. This exercise of enforcement discretion would permit wholesalers and retailers to sell most of their existing inventory of non-IP-compliant cigarettes, thus decreasing the volume of product returns.

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[74] The number of dealers and stamping agents is taken from the Proposed Regulation's RIS at 1.

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With reference to the exercise of such enforcement discretion, the Regulation also could provide a date certain (on or prior to the effective date) after which non-IP-compliant product could not be tax stamped for sale or distribution in New York. The Regulation also could include provisions that prohibit the stockpiling of non-IP-compliant cigarettes prior to the effective date.

H. Comments on PM USA's Costs Related to Compliance with the Regulation.

Although PM USA supports the adoption of a New York State standard on cigarette IP, compliance with the regulation will impose significant costs on PM USA.[75] PM USA estimates that it has incurred and will incur significant additional costs to comply with the proposed New York State regulation. These costs are in three categories: (1) operating costs; (2) testing costs; and (3) preparation costs.

In sum, PM USA estimates that it will experience multiple millions of dollars in one-time compliance costs and a similar amount of increased annual cost.

1. Operating costs. PM USA will incur additional operating costs because of the increased costs associated with cigarettes that comply with the proposed regulation. The main component of increased cost stems from the use of banded paper in place of conventional paper. PM USA also has already incurred substantial costs to develop banded paper.[76] Compliance with the New York regulation also will require PM USA to use different packaging on cigarettes sold in New York. PM USA has already purchased new tooling for use in printing that packaging.

2. Testing costs. Compliance with the New York regulation will require cigarette IP testing on an ongoing basis. The level of annual costs will depend in part on the number of IP groups that must be tested.

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[75] See also *supra* at 30, note 57 (describing other costs related to the Proposed Regulation).

[76] The RIS states OFPC has lacked the cost information needed to assess manufacturers' production costs because of lack of access to proprietary information. RIS at 4. However, OFPC has not requested such information from PM USA, including with any necessary protection for trade secret and other confidential information afforded by Public Officers Law, § 87(2)(d). PM USA is willing to supply such proprietary information, provided that it is accorded appropriate confidential treatment.

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3. Preparation costs. PM USA personnel have been working diligently to redesign cigarettes, including their paper specifications, to comply with the New York regulation.

None of the foregoing costs have been addressed in the RIS as required pursuant to the State Administrative Procedure Act, § 202-1(2)(c)(i).

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Appendix A. Comparison of NIST Extinction Test versus ASTM Extinction Test.

- **The NIST Test and the ASTM Test are different.**
- **Testing by PM USA indicates that the ASTM Test produces significantly higher PFLB values than the NIST Test.**
- **For cigarettes with an actual mean PFLB of 25 by the NIST Test, the expected PFLB using the ASTM Test is 40 to 50 PFLB.**
- **The difference in test results is likely attributable to cigarette orientation post lighting, which is vertical in NIST and horizontal in ASTM.**

The NIST 10 layer extinction test is described in *NIST Technical Report 1436.* The test specified by the proposed standard is the 10 layer extinction test in *ASTM E2187-02b.* Virtually all of PM USA's extinction testing has been done by the NIST Test.[77] These methods are summarized in a table at the end of this appendix. The NIST Test has been used by PM USA, by NIST itself, and by the State of New York at the Kidde-Fenwal laboratory in preparing the proposed standard. By contrast, PM USA is not aware that the ASTM Test has ever been conducted except for very recent testing it has just undertaken.

PM USA has recently conducted the ASTM 10 layer Test in its own laboratory and compared the results to the results of the NIST Test that was conducted at the same time with the same cigarettes. Three cigarette prototypes were used, and eight trials of 40 cigarettes were conducted for each test. The summary results are shown in the graph below. The individual trial results for each prototype are shown in the following graphs. The first graph summarizes the results, showing the cumulative mean PFLB for all the cigarettes. The next three graphs show the individual test trial results.

[77] PM USA has implemented this test with minor modifications to increase throughput or to comport with practices PM generally uses for cigarette testing.

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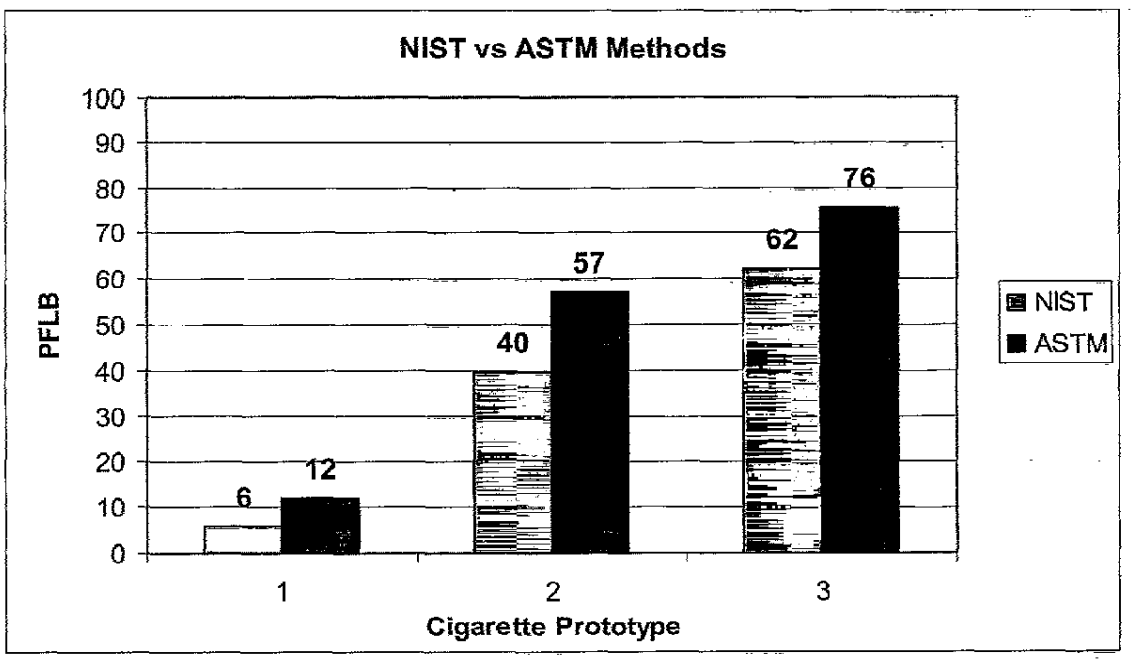

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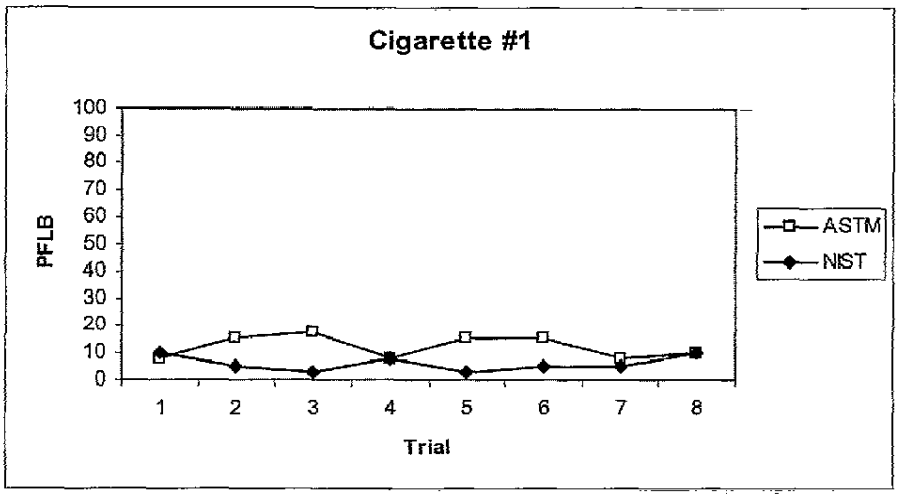

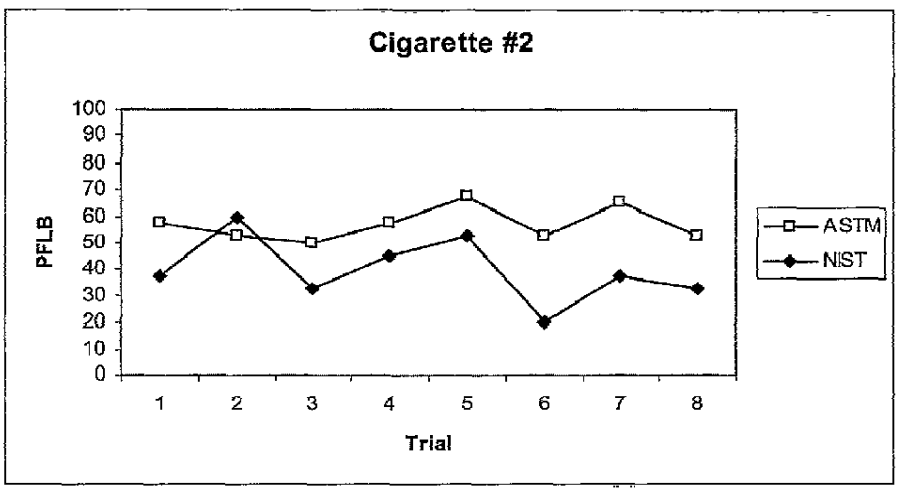

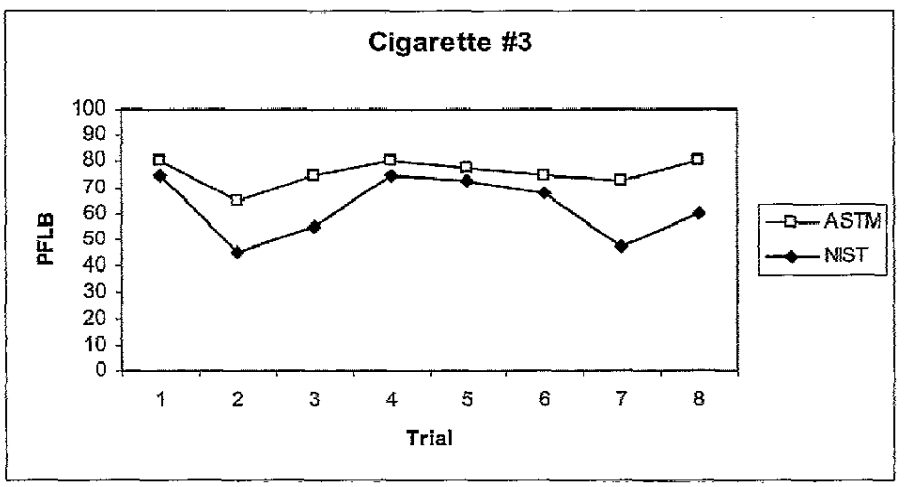

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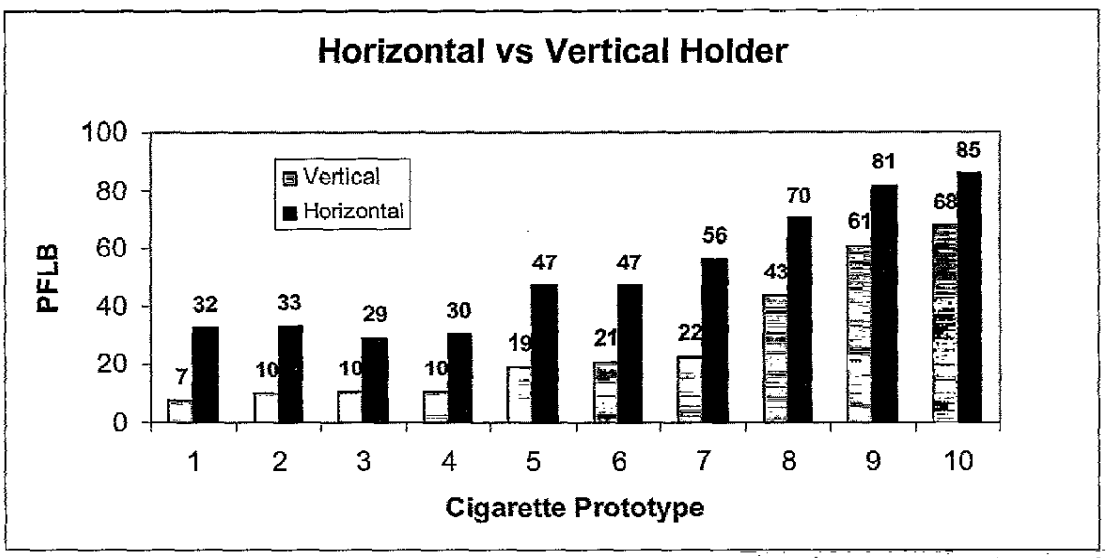
The ASTM Test consistently gives higher values of PFLB by an amount that varies with PFLB, with a maximum mean difference of 17 PFLB. The most likely cause of the difference is that in the ASTM Test the cigarette is held in the horizontal position prior to laying on the filter paper, whereas in the NIST Test the cigarette is held in the vertical position. This explanation is supported by a test PM USA designed that was conducted by Meritus Laboratories, Inc. ("Meritus Laboratories"), a contract testing facility that PM USA has used extensively for ignition propensity testing. The NIST Test was compared to the NIST Test altered only by holding the banded paper cigarette horizontal prior to placing on the filter paper as per the ASTM Test. Ten different cigarette prototypes were used. One trial of 192 cigarettes was used to determine PFLB for each cigarette. The results of the test are shown in the graph below. Horizontal holding consistently gives higher values of PFLB by a difference of at least 17 PFLB and as much as 34 PFLB.



PM USA has also conducted tests using thermal imaging of the cigarette coal. These tests found that banded cigarettes initially held horizontally smoldered at a higher temperature while in the holder. This work supports its finding that horizontal holding is a significant difference between the NIST and ASTM tests.

The testing that PM USA has done demonstrates that the ASTM Test gives a higher value for PFLB than does the NIST Test. PM USA has not conducted any ASTM tests on non-banded cigarettes with PFLB in the range near 25 PFLB, so it is not certain that its finding of elevated PFLB values on the ASTM test will hold for all reduced ignition propensity cigarette designs. Based on the testing it has done, PM USA estimates that a cigarette that measures 25 PFLB on the NIST test will measure from 40 PFLB to 50 PFLB on the ASTM test. This increase in PFLB is comparable to the expected increase in PFLB expected if 3 layers of filter paper are used instead of 10. It is doubtful that the ASTM Test anticipated that changing the cigarette orientation in the

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holder would change PFLB so substantially. In the body of the ASTM Test, it is noted that the ASTM Test and the NIST Test are "nearly identical" (*ASTM E2187-02b 13.1).* This claim is contrary to the results of the testing done by PM USA.

PM USA has not conducted any long term testing of its factory production cigarettes using the ASTM Test. PM USA does not know what the impact of changing to the ASTM test will be on the run-to-run product variability, but expects that the variability will still be evident.

The ASTM Test is a new test, published in December of 2002. PM USA has conducted the ASTM Test, and, based on its results and experience, plans to propose to ASTM revisions to this test to address the following issues. However, PM USA will not propose to ASTM to change the cigarette orientation. When PM USA ran the test, it was not able to follow it exactly because no filter paper exists that meets the weight specification. PM USA will propose that the specification be changed. Also, there is a requirement that no more than two cigarettes be burning at one time in the holder. This requirement is impractical for the required throughput of its laboratory. PM USA typically has four to six cigarettes in the holding position at one time, and it will propose this be allowed. PM USA will also propose that the requirement to store cigarettes in a freezer be modified. This is unneeded except for very long term storage, and is difficult to meet with PM USA's throughput requirements. PM USA will also propose that the ASTM conduct a ruggedness test per *ASTM E1169 Standard Guide for Conducting Ruggedness Tests* to determine environmental and other laboratory conditioning effects and are prepared to assist in conducting such a test. Finally, ASTM relied on the NIST and ASTM Tests being virtually identical in developing the precision statement found in *ASTM E2187-02b.* PM USA's testing shows that the two tests produce different results. Therefore, PM USA will propose to ASTM that it conduct an interlaboratory study to determine the test precision in accordance with ASTM Standard E691-99, *Standard Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method.* PM USA offers to assist in the development of such a study and to participate as well.

The table on the next page summarizes the methodology of the NIST and ASTM Tests. The first column is the methodology of the NIST Test. The second column describes how PM USA's Product Testing Laboratory ("PTL") implements the NIST Test. The third column is the methodology of the ASTM Test. The fourth column describes how PM USA's Product Testing Laboratory ("PTL") implements the ASTM Test. Philip Morris USA has implemented both the NIST and ASTM methods with minor modifications in order to increase throughput or to comport with practices PM USA generally uses for cigarette testing.

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	NIST 1436	PTL - NIST	ASTM E2187-02b	PTL - ASTM
Number of cigarettes per test trial	Not specified	40, 48, 96, 192	40	40
Environmental Conditions	RH: 55 ± 5% Temp: 23 ± 3 °C	RH: 55 ± 5% Temp: 23 ± 3 °C	RH: 55 ± 5% Temp: 23 ± 3 °C	RH: 55 ± 5% Temp: 23 ± 3 °C
Cigarette weight selection required	Yes	No	No	No
Filter paper conditioning	1 week in box	At least 24 hours removed from box – they usually sit for ~ 1 week prior to use	1 week in box or 8 hours for 15 spaced 1 mm apart	1 week in box or 8 hours for 15 spaced 1 mm apart
Weight requirement of filter paper batches	Not required	Not required	24.7± 0.5 g for 15 layers – dry	Not required (Filter paper cannot meet ASTM specification)
Air flow requirement for ignition system	1000 ± 50 ml/min	Sufficient air flow	Sufficient air flow	Sufficient air flow
Cigarette lighting	Butane gas lighter	Electric lighter	Butane gas or electric lighter	Electric lighter
Cigarette marking	15 mm	15 mm	5 and 15 mm	5 and 15 mm
Cigarette lighting	3 seconds	3 seconds	Not to pass 5 mm mark	Not to pass 5 mm mark
Cigarette orientation in holder	Vertical	Vertical	Horizontal	Horizontal
Time and length recording	Required	Not required	Not required	Not required
Concurrent determinations	No restriction	No restriction (normally 4-6 are in pre-burn stage)	Not more that 2 cigarettes in pre-burn stage	No restriction (normally 4-6 are in pre-burn stage)
Plastic or rubber gloves	Required	Not required	Required	Not required
Cigarette conditioning	Vertical in 250 ml jars	Vertical in 250 ml jars	Vertical in 250 ml jars	Vertical in 250 ml jars
Cigarette storage	Storage in freezer after 1 week	Storage at room temperature (~ 6 months)	Storage in freezer after 1 week	Storage at room temperature (~ 6 months)
Test Chamber				
Thickness	6 mm	5 mm	6 mm	6 mm
Inside height	340 ± 2 mm	344 mm	340 ± 2 mm	340 mm
Inside width	292 ± 2 mm	292 mm	292 ± 2 mm	292 mm
Inside depth	395 ± 2 mm	395 mm	395 ± 2 mm	395 mm
Chimney height	178 ± 2 mm	191 mm	178 ± 2 mm	178 mm
Chimney diameter	150 ± 2 mm	155 mm	150 ± 2 mm	150 mm
Filter paper holder				
Outer diameter	165 ± 1 mm	165 mm	165 ± 1 mm	165 mm
Inner diameter	127 ± 1 mm	130 mm	127 ± 1 mm	127 mm
Height	50 ± 1 mm	56 mm	50 ± 1 mm	50 mm
Recess in top	8 ± 1 mm	14 mm	8 ± 1 mm	8 mm
Expanded inner diameter	152 ± 1 mm	150 mm	152 ± 1 mm	152 mm
Legs	20 mm	20 mm	20 mm	20 mm
Metal rim				
Outer diameter	150 ± 2 mm	150 mm	150 ± 2 mm	150 mm
Inner diameter	130 ± 2 mm	128 mm	130 ± 2 mm	130 mm
Thickness	3 ± 1 mm	5 mm	3 ± 1 mm	3 mm

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Appendix B. Merit Production Extinction Test Data.

- **The actual mean PFLB for Merit production cigarettes is about 25 PFLB or less for six of seven Merit brands frequently tested.**

- **Run-to-run product variability is significant.**

- **ASTM Test stated reproducibility severely underestimates test result variability when production cigarettes are used.**

PM USA has been selling cigarettes with banded paper nationwide for over two years in its Merit brand. It has tested the ignition propensity of those cigarettes sampled from its production at approximate monthly intervals. PM USA has used the *NIST Technical Report 1436* 10 layer extinction test and has used trial sizes of both 96 and 48 cigarettes, the latter of which is similar to the 40 in the proposed standard. These are the results from those tests for the seven Merit brands that were regularly tested using the NIST Test from mid 2001 through 2002.

	Merit LT KS	Merit LT 100 Reg	Merit UL KS Men	Merit UL KS Reg	Merit UL 100 Reg	Merit ULTM KS Reg	Merit ULTM 100 Reg
Total number of test trials	14	16	12	17	15	11	14
total cigarettes	912	1008	720	1104	960	768	912
test mean PFLB	34.38	27.47	25.61	14.71	20.07	7.29	7.51
std deviation	15.40	22.88	16.66	13.42	22.03	6.30	10.36
std error	4.11	5.72	4.81	3.25	5.69	1.90	2.77

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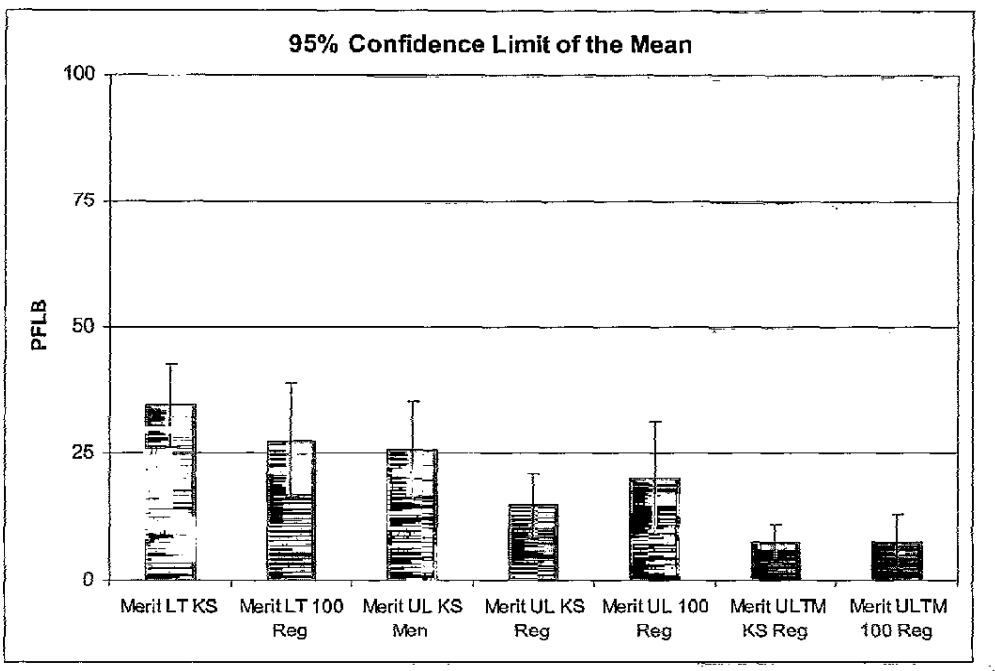
Source: https://www.industrydocuments.ucsf.edu/docs/gyhk0001

Below are the results presented graphically indicating the cumulative test mean PFLB and the 95% confidence limit of the cumulative test mean for each brand style.



The cumulative test mean PFLB of four of the Merit brands is below 25 PFLB. Of the three brands that exceed 25 PFLB, two of the brands (Merit LT 100 Reg and Merit UL KS Men) have a cumulative test mean PFLB that is not statistically different from 25 PFLB as indicated by the 95% confidence bands. For example, the test mean PFLB for the Merit UL KS Men is 25.61. The actual production mean is 95% likely with the range of 16.2 and 35.0 PFLB. All of the brands, with the exception of the Merit Ultima KS Reg, exceeded 25 PFLB on at least one trial, as is shown in the plots below of the test trial results for each brand style plotted at approximate monthly test intervals.

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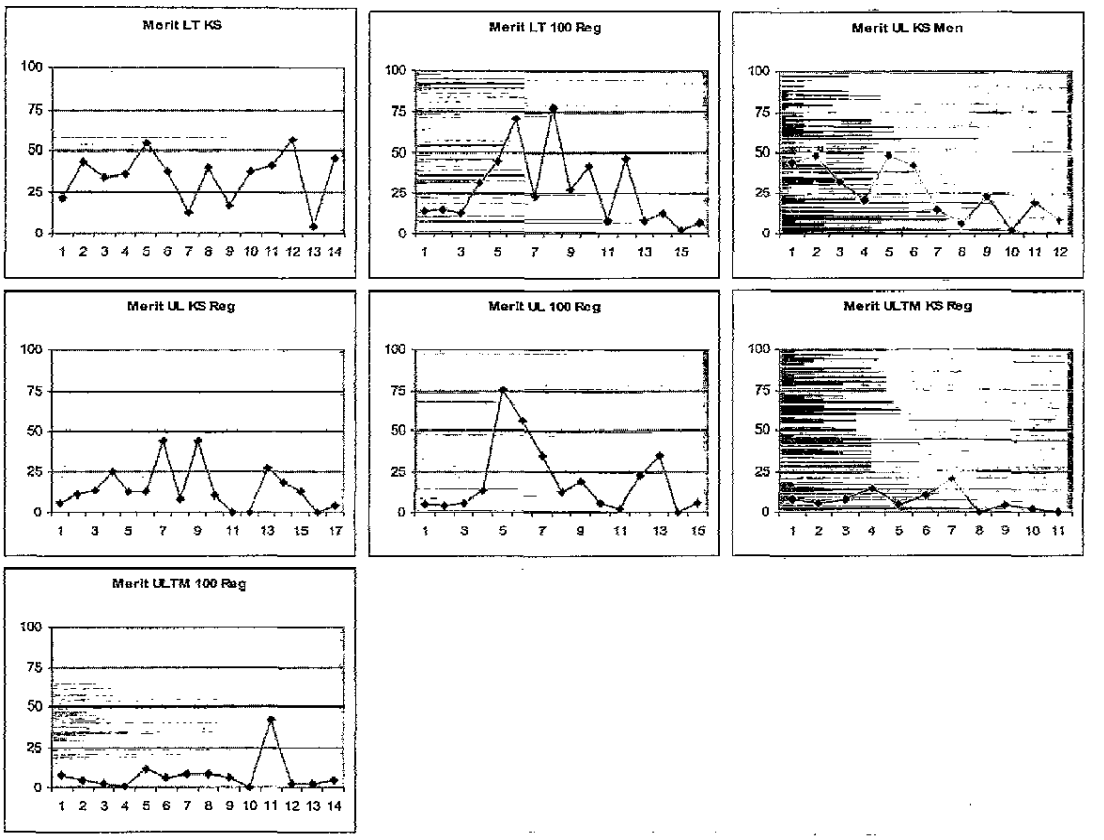

The test results show a significant variation in PFLB. Individual test trials gave PFLB values in excess of 70 PFLB on occasion. For the Merit ULTM 100 Reg, all values of PFLB were 12 PFLB or less, except for one value of 42 PFLB.

The test results demonstrate the product variability over production runs. Cigarettes made to the same specifications in different production runs over time are not identical. Variation in the materials used such as tobacco and paper, which are agriculturally-based or -derived, along with variations in the manufacture of the tobacco rod, lead to an overall variation in the cigarette. This variation is present in all cigarettes, not just ones with banded paper. Because non-banded cigarettes often have PFLB values of 100 PFLB when measured with the NIST Test, the variation of the cigarettes is not evident.

The magnitude of the run-to-run variability of factory produced cigarettes can be better appreciated by contrasting to the variability of the extinction test method itself. The total variability can be expressed as the run-to-run reproducibility, which accounts for both variation in the cigarettes as well as variation in the test itself due to differences among operators, laboratory conditions, and the binomial nature of the test itself. The test reproducibility is calculated from 2.77 times the test standard deviation, AMERICAN

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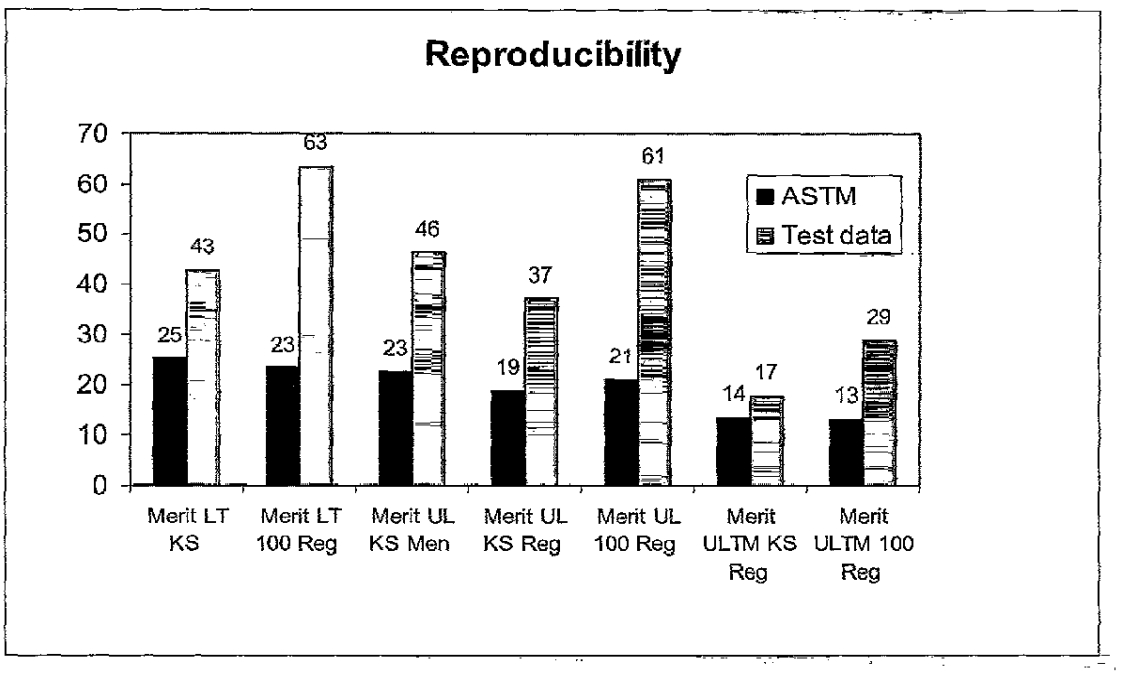
SOCIETY OF TESTING AND MATERIALS, STANDARD E177-90A: STANDARD PRACTICE FOR USE OF THE TERMS PRECISION AND BIAS IN ASTM TEST METHODS § 27.3.3 (1996), and is shown on the graph below. For comparison, the corresponding values of the reproducibility from Table 1 of *ASTM E2187-02* (multiplied by 100 to convert to percent) are also shown. The ASTM reproducibility values take into account all the variation expected in the test results except the run-to-run variability of the cigarettes.



Reproducibility can be defined in a number of ways. The definition used in *ASTM E2187-02* is that the difference of the results from any two trials is 95% likely to be less than the reproducibility interval. For example, for the first brand style in the graph (Merit LT KS), the ASTM reproducibility is 25 PFLB. That means that the expected difference between PFLB values of any two trials is 95% likely to be 25 PFLB or less per ASTM. The test trial reproducibility is 43 PFLB, meaning that differences between trials as high as 43 PFLB are expected. Considering all the brand styles, the reproducibility of the test trials is much worse than predicted by ASTM. The mean value for the test data is 42 PFLB. The mean value is 20 PFLB for ASTM. The difference shows that run-to-run product variability is significant, and is much greater in magnitude than the underlying test variability stated in the ASTM Test.

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Appendix C. Grouping of Cigarettes.

- **Cigarettes may be grouped for testing based on similarity of one or more design features.**

- **The benefits of grouping are improved statistical confidence because more tests can be conducted on a group than on a brand style, reduced overall testing load, and reduced certification and reporting burden.**

The Merit brands can be clustered into three groups based on FTC tar level: Merit Lights, Merit Ultra Lights, and Merit Ultima. The major cigarette design parameter that affects PFLB that differs among the groups is tobacco packing density, which is highest in Lights, and lowest in Ultima. Grouping also allows additional Merit brand styles to be included even though they were only tested infrequently. A total of 13 brand styles were included in the groups. The results for the groups are given below in the same manner as was done for the individual brand styles.

	Merit Lights	Merit Ultra Lights	Merit Ultima
Brands in Group	Merit LT KS Reg SP (8 mg FTC tar) Merit LT KS Reg RCB (8 mg FTC tar) Merit LT 100 Reg SP (10 mg FTC tar) Merit LT 100 Men SP (10 mg FTC tar)	Merit UL KS Men SP (5 mg FTC tar) Merit UL KS Men SP (5 mg FTC tar) Merit UL KS Reg RCB (5 mg FTC tar) Merit UL KS Reg SP (5 mg FTC tar) Merit UL 100 Reg SP (6 mg FTC tar)	Merit ULTM KS Reg SP (1 mg FTC tar) Merit ULTM KS Reg RCB (1 mg FTC tar) Merit ULTM 100 Reg SP (2 mg FTC tar) Merit ULTM KS Reg RCB (2 mg FTC tar)
Key	LT = Light, UL = Ultra Light, ULTM = Ultima, KS = King Size, Men = Menthol, SP = Soft Pack, RCB = Rounded Corner Box	LT = Light, UL = Ultra Light, ULTM = Ultima, KS = King Size, Men = Menthol, SP = Soft Pack, RCB = Rounded Corner Box	LT = Light, UL = Ultra Light, ULTM = Ultima, KS = King Size, Men = Menthol, SP = Soft Pack, RCB = Rounded Corner Box
Tobacco packing density mg/cc	247	225	177
Number of test trials of 96	11	15	10
Number of test trials of 48	25	33	19
Total number of test trials	36	48	29
total cigarettes	2256	3024	1872
test mean PFLB	28.10	19.16	6.90
std deviation	19.47	17.26	8.19
std error	3.25	2.49	1.52

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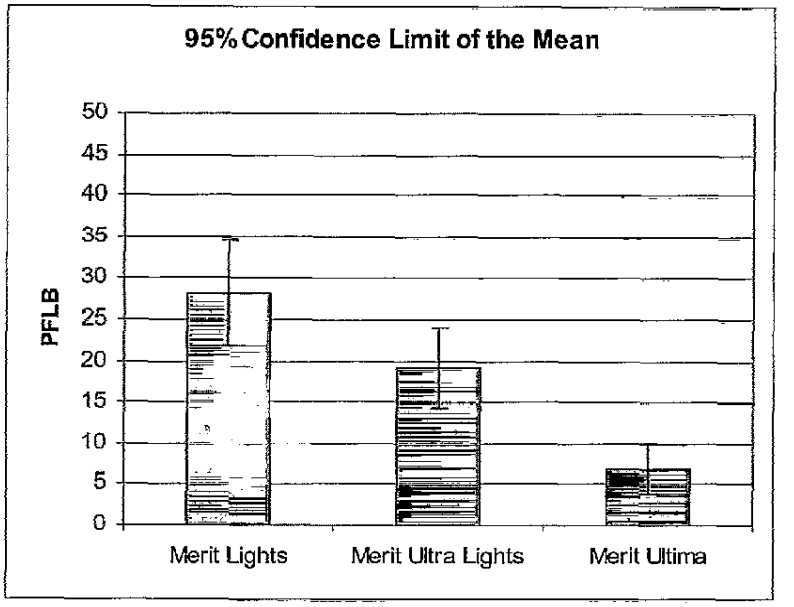

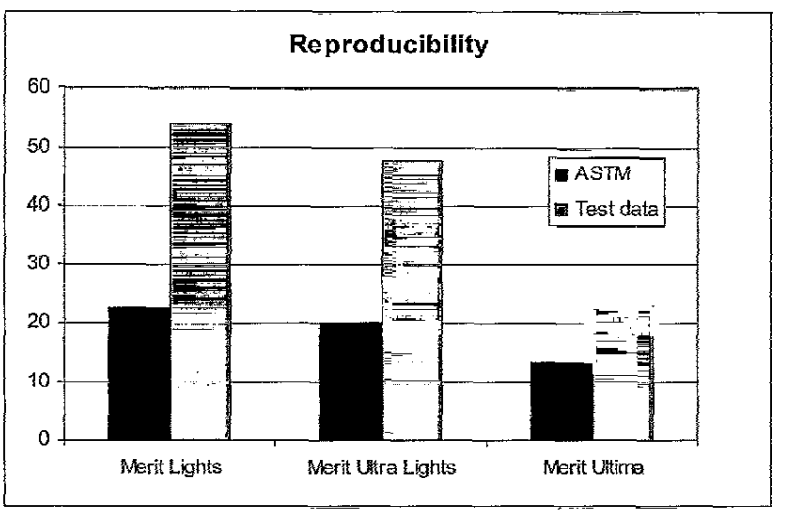

All of the three groups have a cumulative test mean PFLB either under 25 PFLB or statistically not different than 25 PFLB. The PFLB decreases with decreasing tobacco packing density, as expected. The standard error and hence the 95% confidence intervals are smaller than for the individual brand styles. The reproducibility shows the same large difference relative to ASTM that was shown with the individual brand styles.

The grouped data shows the same results as the individual brand style data, but does so in a compact manner. Less noise is present in the grouped data due to the greater number of trials.

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This example is but one of many possibilities for grouping. The cigarettes in each group are similar in tar and design, but not identical. Another type of grouping would be to put brands of identical design together, while yet another is to put brands with identical design with respect to important parameters that affect PFLB such as tobacco blend, circumference, and rod density together. Irrespective of the specific manner of grouping, the benefits of grouping are improved statistical confidence because more tests can be conducted on a group than a brand style, reduced overall testing load, and reduced certification and reporting burdens.

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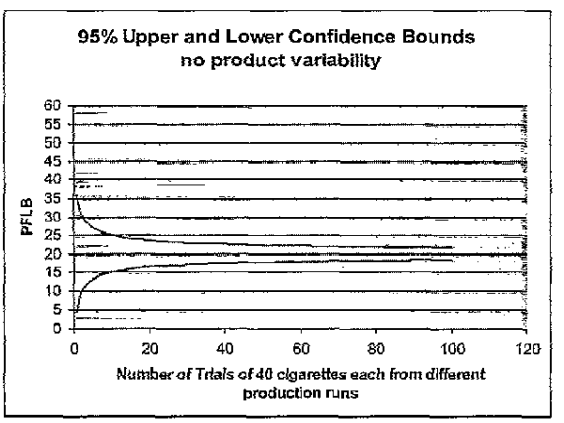
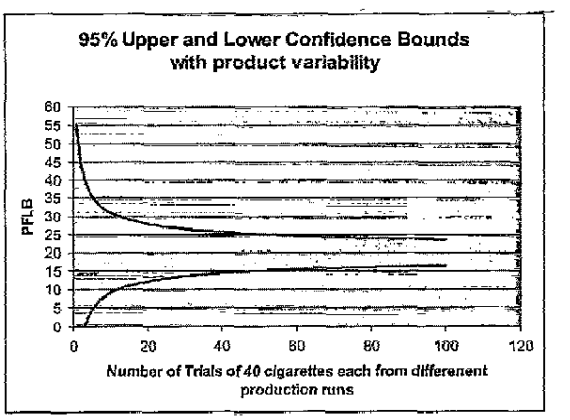
Appendix D. Effect of Product Variability on PFLB.

- **Product variability increases the maximum expected PFLB from a single test trial.**

- **Product variability degrades the ability to determine the actual production mean from a small number of test trials.**

The importance of the run-to-run product variability is manifested in two ways. First, on a single test trial, the range of possible results enlarges. Second, the ability to determine the actual production mean PFLB from a small number of test trials is degraded. These two effects are shown in the graphs below. The first graph is for a cigarette with an actual production mean PFLB of 20 and a standard deviation of 8 (estimated from ASTM reproducibility). This calculation is intended to simulate a cigarette with no run-to-run variability. The actual mean PFLB value is set below 25 PFLB so that the cumulative test mean can achieve a value less than 25 PFLB with reasonable confidence. The second graph is from calculations of a hypothetical cigarette with an actual production mean PFLB of 20, and an assumed test standard deviation of 18 (value estimated from test data for a Merit brand style with a comparable PFLB), and incorporates run-to-run product variability.





Where there is no product variability, the highest expected value of PFLB (based on 95% confidence limit) is 35 PFLB, and the cumulative test mean is expected to be below 25 PFLB after about 10 trials. With product variability, the highest expected value is 55 PFLB, and the number of trials needed to achieve a cumulative test mean of 25 PFLB or less at a 95% confidence level is more than 50 test trials.

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Appendix E. Quality Control.

- **The 19% PFLB repeatability criterion in the proposed standard cannot be met with production cigarettes.**

- **There should be requirements for accuracy, precision and laboratory certification.**

- **A standard reference banded cigarette of 25 PFLB should be developed and used to measure laboratory accuracy and precision.**

- **PM USA supports the need for a reference cigarette even if it is not involved in its design or production.**

- **Laboratories should pass an interlaboratory comparison per ASTM E691.**

- **PM USA is prepared to assist and expedite the development of its proposed requirements. PM USA believes that only one year is needed.**

The role of product variability is not accounted for specifically in the proposed standard with regard to the repeatability requirements of the test in the proposed standard, which specifies a 19 PFLB repeatability. The repeatability is similar to the reproducibility but applies only to a single laboratory, ideally with a single operator. The testing requirements of PM USA are such that multiple operators must be used, therefore the reproducibility is a more appropriate criterion. This value of 19 PFLB was generated by NIST in *NIST Special Publication 851* which was cited by the *ASTM E2187-02b* standard. It is based on tests of cigarettes made at a point in time and is not realistic for tests done on production cigarettes manufactured over the course of time. Furthermore, these tests did not use cigarettes with banded paper. PM USA has tested seven brands of Merit cigarettes for two years and cannot achieve the proposed level of repeatability because of product variation. PM USA's mean reproducibility is 43 PFLB. The proposed requirements for quality control of the laboratories doing the ignition testing cannot be met by testing production cigarettes.

PM USA believes that the standard should address three critical aspects of laboratory quality: accuracy, precision, and laboratory certification. Accuracy is not all addressed in the proposed standard. PM USA wants the test to be accurate and believes there should be a requirement for accuracy against an accepted reference standard cigarette. The *ASTM E2187-02b* standard is accurate, because it defines ignition strength. But that does not mean that any laboratory conducting the test will do so in a way that produces accurate results. An improperly conditioned laboratory will produce inaccurate results. These errors may not reveal themselves in the repeatability or values, because conditions may be tightly controlled, but to the wrong values. PM USA has been conducting tests in two laboratories: its own, and in a contract laboratory, Meritus Laboratories. Both have been conducting the NIST Test for over a year. PM USA finds that the Meritus Laboratories tends to provide PFLB values lower than its own laboratory

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and that this difference is statistically significant. Differences of about 10 PFLB are not uncommon. The results of an interlaboratory study are summarized in the table below.

	cigarette 1	cigarette 2
mean PFLB - Philip Morris USA Product Testing Laboratory	21.90	73.20
mean PFLB - Meritus	14.10	56.30
SD R (per ASTM E691)	4.75	13.50
ASTM SD R (R/2.77)	7.58	8.66
R (Reproducibility)	13.16	37.40
ASTM R (E2187 table 1)	21.00	24.00

PM USA does not know the root cause of the difference in the test mean PFLB, but suspect that there are variables of importance to PFLB that are not adequately controlled for in the NIST Test. PM USA does not know if the ASTM Test is any improvement in this regard.

PM USA believes that a laboratory should prove its accuracy by conducting control cigarettes of known PFLB. PM USA could manufacture and provide these cigarettes and distribute them through NIST or the University of Kentucky. NIST is the source of many primary calibration standards used throughout science and industry, and the University of Kentucky has been supplying reference cigarettes to industry, government, and academia for over thirty years. The design and target PFLB of the cigarette could be worked out in consultation with NIST. PM USA proposes to incorporate banded paper on at least one of the reference cigarettes because that is the technology with which PM USA has experience; OFPC also may want to consider other technologies for an additional reference cigarette. PM USA support the need for a reference cigarette even if it is not involved in its design or production. Product variability could be minimized by manual inspection of materials, using a single lot of a tobacco blend, inspection of finished cigarettes, and extensive extinction testing of the finished cigarettes. Precision can also be measured using the reference cigarette, and those results can be used to set the standard for precision. Precision should be evaluated by using reference cigarettes, rather than commercial cigarettes because the unknown underlying product variation of commercial cigarettes obscures the results. The reproducibility of the test method should be assessed with an interlaboratory study comprising industry, contract, and government laboratories. The design of the study should follow accepted practices, for example: *ASTM E691-99 Standard Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method.* Laboratories that successfully participate in such a study should be certified to test cigarettes for the purpose of the standard.

PM USA is prepared to begin consultation and design of a reference cigarette immediately, if need be. The time required to design, manufacture, and test such a cigarette is about six months. PM USA is also prepared to participate in an interlaboratory study per *ASTM E691-99* and is willing to assist in its planning and execution. Such a study would ideally include eight laboratories, but could be done with as few as six. PM USA knows of four laboratories conducting extinction testing: Philip

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Morris Product Testing Laboratory, Meritus Laboratories, NIST, and Kidde-Fenwal. With the addition of other industry, government, and contract laboratories, it should be possible to achieve the requisite number. PM USA estimates that such an interlaboratory study could be completed in six months, once a reference cigarette is made.

All of these necessary requirements for accuracy, precision, and laboratory certification could be achieved within one year.

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